DEA Compliance Manual



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DEACOMPLIANCE MANUAL

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PREFACE

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotics and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drugs and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Prevention Control Act of 1970 (the "Controlled Substances Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The thrust of this Controlled Substances Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- recordkeeping requirements;
- manufacturing quotas;
- distribution restriction;
- · dispensing restrictions;
- limitations on imports and exports;
- · conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable by up to 15 years imprisonment and \$10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

This manual is intended as a resource to the Controlled Substances Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has a tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs Part 1300 to End -- available from:

Superintendent of Documents U.S. Government Printing Office Washington, D.C. 20402 (202) 783-3238

ARCOS Reporting Manual -- available from:

United States Department of Justice Drug Enforcement Administration ARCOS Unit, P.O. Box 27273 Central Station Washington, D.C. 20038-7273 (202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

INTRODUCTION

The Controlled Substances Act and implementing regulations (21 CFR 1300 to the end) impose a substantial number of requirements upon wholesalers and other handlers and prescribers of controlled drugs. This training manual deals with the records of controlled drug transactions that must be kept by wholesalers and the reports that wholesalers must submit. The theory behind the records requirements for Schedule III through V controlled drugs is that a registrant's regular, normal business records are acceptable provided that they contain all necessary elements of information and that these elements are readily retrievable from the records (more later on retrievability). Special, separate records are required from Schedule II controlled drugs (see Biennial Inventory and Order Forms). The importance of accuracy in taking required inventories and in recording controlled substances transactions should be stressed to wholesaler employees charged with these responsibilities.

11/27/95

Records and Reports - Introduction

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INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand in live, morgue and brokerage.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Changing Inventory Date. To coincide with a fiscal year, year-end ARCOS inventory, general inventory time, or any other reason, the wholesaler may change the controlled drug inventory date to another fixed date provided that the new is within two years of the previous biennial date. DEA does not have to be notified.

Cardinal Health had received prior authorization from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years and will continue to do so. Refer to DEA correspondence 11/21/96.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand in live, morgue and brokerage.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the DEA by January 15th of the following year.

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Inventory

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Periodic

(21 CFR 1304.11, 21 CFR 1301.74)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. (21 CFR 1304.11 (d))

Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.

Required Inventory Records. The inventory must be maintained in written, typewritten, or printed form. It should be signed by those taking the count and both the date of the inventory and whether it was taken as of the opening of business or close of business must be recorded. Inventories of all Schedule I (research drugs) and Schedule II substances must be separated from inventories for all other substances. Schedule III through V substances may be maintained separately from all other substances or in a readily retrievable manner. Readily retrievable means that the records (whether ADP, electronic, or mechanical are kept in such a manner that they can be separated out in a reasonable time and/or the items are identifiable visually from other items appearing on the records (asterisk, redlined, etc.).

For each controlled substance in finished form, the required inventories must contain:

- Name of the substance;
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter;
- Number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
- Number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

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For controlled substance returns, damaged goods, or substances awaiting disposal, the inventory must contain:

- Name of the substance;
- Total quantity of the substance to the nearest metric unit of weight or the total number of units of finished form; and
- Reason for the substance being maintained by the registrant.
- (21 CFR 1304.22 (b), 21 CFR 1304.11(2))

Count Requirements. When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of-balance item.
- Run audit report for any out-of-balance item.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Retention of Inventory Records. The records must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. (21 CFR 1304.04)

Note: State record keeping requirements may be more than two years and should be maintained accordingly.

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Inventory

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DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

<u>Prefix.</u> 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). (Refer to DEA Correspondence 8/25/93). The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

<u>Suffix</u>. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	В
February 28	S		C. E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

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DEA Registration

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DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA Certificate of Registration (Exhibit J). DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration (Exhibits K, L). A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The Quarterly DEA Exception Report (Exhibit N) is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office will check this type of situation. Calls to the local DEA office should be documented on a Regulatory Agency Contact Form (Form #1).

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.

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DEA Registration

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Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. (21 CFR 1301.51)

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a Limited Power Of Attorney (Form #25) that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the Power Of Attorney and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. Refer to DEA Correspondence 8/25/93.

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred.
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

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DEA Registration

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Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

<u>Prefix.</u> The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

<u>Suffix.</u> The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

- W Manufacturer
- Y Distributor
- V Retail Distributor
- X Importer
- Z Exporter

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DEA Registration

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MAINTENANCE OF RECORDS

The wholesaler is required to maintain on a current basis a complete and accurate record of every controlled substance received, distributed, or otherwise disposed of. Separate records are required for each registered location. Records of Schedule I (research drugs) and II drugs must be maintained separately (see section on Order Forms). All required records must be retained for two years. (21 CFR 1304).

Required Record Information

(21 CFR 1304.22 (b))

The following information is required for each controlled substance:

- Name of the substance.
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- Number of commercial containers of each such finished form received from other
 persons, including the date of and number of containers in each receipt and the
 name, address, and registration number of the person from whom the containers
 were received.

Note: Many wholesalers have been cited for failing to record the actual date of receipt on the document of transfer (e.g., invoice or packing slip) as well as the accurate name, address and registration number of the shipper.

Number of commercial containers of each such finished form distributed to other
persons, including the date of and number of containers in each distribution and the
name, address and registration number of the person to whom the containers were
distributed.

Note: Wholesalers also have been cited for failing to record the actual shipping date as well as the accurate name, address, and registration number of the person to whom it was shipped. Ditto marks on DEA Form 222 are not acceptable for recording dates.

Note: When providing backup service for another division, and shipping directly to the division's customer, your records must show that

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customer as the recipient of the product. Refer to DEA Correspondence 6/28/95.

Number of units or volume of finished forms and/or commercial containers
distributed or disposed of in any other manner (e.g., by distribution as
complimentary samples or by destruction) including the date and manner of
distribution or disposal, the name, address and registration number of the person to
whom distributed, and the quantity of the substance in finished form distributed or
disposed of.

Automated Records Systems

Federal requirements can be met by either automated or manual records systems provided that the specific system contains all the necessary data elements. The wholesaler has the option of maintaining records for Schedule III through V transactions either separately or, if they are readily retrievable, with noncontrolled drug transactions. Ready retrievability requires that the records (whether an automated system, a manual system or a combination) clearly identify controlled drug transactions so that they can be extracted readily (i.e., identified by schedule symbol (C-III) or asterisk, redlined, on separate invoices for controlled drugs only, etc.).

Returns from Customers or to Manufacturers

Care must be taken to ensure that all the data elements are included on records for returns. These records must have the same information as that required on all receiving/shipping records including the name, address, and registration number of the customer/supplier, the name of the substance, each finished form, the number of units or volume and the number of containers; and the actual date the substance was received by the wholesaler or returned to the supplier. Schedule II returns must be made pursuant to a valid order form (see section on Order Forms).

Note: Wholesalers often fail to place the required information on return documents or to maintain Schedule III through V returns records in a readily retrievable manner.

Rules for Central Record Keeping (21 CFR 1304.04)

Recognizing the trend toward the automation of business records in a central data center covering multiple locations, DEA allows financial and shipping records to be kept at a central location following written notification to the DEA special agent in charge of the field office covering the area where the registrant is located. The central records system may commence 14 days after the special agent in charge receives notification (sent in triplicate by certified or registered mail, return receipt requested). The notification must contain the name, address, and registration number of all locations to be included, the name and address of the exact location where the central records will be kept, a brief description of the records system and the records to be maintained centrally, and a statement agreeing

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to make the records available at the registered location within two business days. If there is no response from DEA within 14 days after receipt by the special agent in charge, the wholesaler can proceed with the central records system. The wholesaler must, if DEA chooses, allow inspection at the central location in lieu of delivery to the registered location.

Exception: Inventories for all schedules of controlled drugs and Schedule II order forms must be kept at the registered location.

ARCOS participants wishing authorization to report from other than their registered location must obtain a separate central reporting identifier from the ARCOS Unit, P.O. Box 28293, Central Station, Washington, D.C. 20005, (202) 307-8600.

Microfilm/Microfiche Records

DEA does not consider copies of primary records an acceptable substitute for primary documents due to the opportunity for alteration when copying an original document. However, DEA will consider for approval on a case-by-case basis any system that simultaneously generates the copy and the original record. Approval of such a system requires DEA access to readers and printers as well as to the film. If a wholesaler microfilms/microfiches the originals for ease of handling, but retains the originals in backup storage for two years, this would satisfy DEA concerns as the originals could be made available for review as needed.

Drop Shipments of Controlled Substances

Wholesaler records of drop shipments are not required because these controlled substances are shipped directly from the supplier to the customer and never enter the wholesaler's possession. All such purchase orders and invoices must be clearly marked as drop shipments and should not be stored with records that document the actual receipt or distribution of controlled substances. Further, Schedule III narcotic substances which are drop-shipped are ARCOS reportable by the supplier on DEA Form 333.

Storage of Records

Care should be exercised to ensure that, for at least the two years they must be retained, all the wholesaler's controlled substances records are maintained in a secure and yet accessible manner. The controlled substance records are as follows:

- Receiving documentation
- Invoices and credit memos
- Narcotic Sales Report
- Narcotic Order Forms (DEA Form 222), brown and blue copies, and related records
- Monthly ARCOS Report
- ARCOS Edit Error Report and submission

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Maintenance of Records

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- Count Sheets from Periodic Inventories
- Suspicious Order Analysis, or Excessive Purchase Report
- DEA Form 106
- DEA Form 41
- Return Receipt Requested forms for any mailings
- Debit Memos for Returns to Vendors
- Year-End ARCOS Inventory
- Biennial Inventory

DEA requires that records be maintained for two years. Record retention requirements for individual states may vary. Additional records may be maintained as required by division policy.

Shipping Errors

Shipping errors must be documented as any normal transfer of controlled substances would be and as mandated by DEA record keeping and reporting requirements. In other words, any transfer of controlled substances, regardless if shipped in error, must be appropriately documented with 222s, invoices, credit memos, and ARCOS reporting as applicable. The swapping of the right product for the wrong product is inappropriate. Each distribution and return must be documented as a separate independent transaction. These requirements apply to intra-company as well as customer shipments. Several examples of shipping error scenarios and the corresponding corrective actions are included as Exhibit Q.

Brokerage Operations

Some Cardinal Distribution facilities have brokerage business operating within their distribution center. The brokerage business operates on the division's DEA registration number, therefore the division is ultimately responsible for compliance with DEA regulatory requirements as they apply to brokerage operations. Key compliance issues related to the division/brokerage operating relationship are as follows:

- Brokerage personnel must coordinate with division personnel to ensure they are following all division procedures related to the receipt, distribution, storage, inventory, etc. of controlled substances.
- All transaction records and reports for brokerage purchases, sales and other
 dispositions of controlled substances must be included in the division's records. On
 the distrack system this is accomplished through a month end records transfer from
 the brokerage system to the division system. HP divisions maintain hard copy records
 and adds ARCOS records through a manual process.
- Records for controlled substance transactions between brokerage and the division are not required records since brokerage operates on the division's DEA registration.
 These records must be deleted from the brokerage and division record keeping systems.

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Maintenance of Records

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- Brokerage controlled substance inventory must be stored in the cage and vault, but is maintained separately from the division's inventory and is identified as brokerage inventory.
- Although brokerage inventory is maintained separately, it must be included in all inventories conducted by the division.
- The division must be licensed, as required, in those states into which they distribute to brokerage customers.
- The division must verify and maintain a copy of all brokerage customer DEA registrations and state licenses.

A more detailed description of brokerage operations is contained in the Brokerage Warehouse Operations Procedures Manual which should be available to you from brokerage personnel located in your division.

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ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O).** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant currently is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the DEA Narcotic Blank Log (Form #4), and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms (21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by
 means of interleaved carbon sheets which are part of the DEA Form 222. Order
 forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler
 may consider rejecting any Form 222 completed in pencil, indelible or not, as the
 identification of indelible over regular lead is tenuous at best.
- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.

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If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.
- The correct name and address of the supplier from whom the controlled substances
 are being ordered is entered on the form. Only one supplier may be listed on any
 one form.
- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to 21CFR 1305.05(c). The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the DEA Narcotic Blank Log.
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the DEA Narcotic Blank Log.

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- Corporate Purchasing receives and stores order forms in a secure area. Corporate
 Purchasing contacts division if numbers are out of sequence or an order form is
 missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations (21 CFR 1305.06).
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor;
 Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

Note: All three copies of voided order forms must be sent to the division.

- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney (21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a Power of Attorney (Form #2) for each such individual. The Power Of Attorney is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a Notice Of Revocation (Form #3), signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms (21 CFR 1305.09)

• The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. Refer to DEA Correspondence 07-18-96.

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- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies I (brown) and 2 (green)the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.
- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.
- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.
- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. Refer to DEA Correspondence 6/29/92.

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution

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center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a **DEA 222 Transmission Log (Form #5)** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are not released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure shall not be used unless the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA will not permit, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. Refer to DEA Correspondence 07-18-96 and 08-28-96.

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

- 1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.
- 2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.
- 3. Cardinal crossdock employee removes 222s from envelopes and completes DEA222 Transmission Log (Form #5).
- 4. Cardinal employee faxes 222s to distribution center. This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.
- 5. Fax is received in distribution center by Operations Manager or designee.
- 6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.
 - a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.

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- 7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.
- 8. Operations Manager or designee delivers faxed 222s to the vault.
- 9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

- 1. Customer faxes 222 directly to the distribution center.
- 2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.
 - a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.
- 3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.
- 4. Operations Manager or designee delivers faxed 222 to the vault.
- 5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.
- The supplier retains copy 1 (brown) of each order form that has been filled.
- Order forms must be maintained separately from all other records of inspection for two years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to (21 CFR 1305.06 (d)) must be kept at the registered location printed on the order form.

Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms

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(21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:
 - (1) Is not complete, legible, or properly prepared, executed, or endorsed; or
 - (2) Shows any alteration, erasure, or change of any description.
- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.
- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with 21 CFR 1305.13. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.
- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.
- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.

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- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to
 the supplier, but the customer's copy must be forwarded to him in advance of the
 shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.
- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code numer is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but
 a single item has a non-correctable defect, this item may be canceled in lieu of
 returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

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Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.
- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an Order Form Rejection Notification (Form #6). The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.
- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser of the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a Narcotic Order Review Form (Form #7) for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

Procedure for Endorsing Order Forms (21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown) and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with 21 CFR 1305.09(b),(c) and (d) including shipping all substances directly to the purchaser.
- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is

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requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (bue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to 21 CFR 1301.45 or 1301.46 of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

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METHAMPHETAMINE CONTROL ACT RECORDKEEPING AND REPORTING REQUIREMENTS (21 CFR 1310)

Pursuant to the Domestic Chemical Diversion and Control Act, DEA has regulated both RX and OTC single-entity ephedrine products since 1994. The Methamphetamine Control Act of 1996 extends these regulations and DEA control to the distribution of OTC combination ephedrine, pseudoephdrine and phenylpropanolamine products. A list of these products covered by the regulations is included as Appendix E.

The requirements which became effective October 3, 1997 are not the same as those for controlled substances. These products will not be scheduled, will not have to be kept in secure storage, and complete inventory accounting and ARCOS reporting requirements do not apply.

The MCA regulatory scheme, described in 21 CFR, Part 1310, has four basic components: registration; keeping records of ephedrine, pseudoephedrine and phenylpropanolamine transactions; reporting any unusual losses or excessive purchases to DEA, and taking steps to be sure the purchaser is legitimate.

Registration

Distributors who handle covered products are required to register as a chemical distributor with DEA, however DEA has exempted anyone with a valid DEA controlled substance registration from having to obtain the additional registration.

Your customers should have either a DEA controlled substance registration or a chemical registration.

Please note that there is a pseudoephedrine and phenylpropanolamine registration exemption for customers who meet the definition of a "retail distributor." Retail distributor is defined as a grocery store, drug store or other entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use (approximately 1200 dosage units), both in number and volume of sales, either directly to walk-in customers or in face to face transactions by direct sale.

The exemption process should be handled on a case by case basis. Customers not currently registered with DEA who believe they qualify for the exemption should be requested to provide written documentation to this effect. Once the documentation is received, the customer can be set up to purchase these items.

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MCA Recordkeeping Requirements

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Note: A review of Cardinal's customer database has indicated that the vast majority of customers currently possess a valid DEA registration. Additionally, customers who do not possess such a registration are of a class that would not typically purchase these products.

Records

You must maintain readily retrievable records of each ephedrine, pseudoephedrine or phenylpropanolamine product transaction for 2 years. Normal business records shall be considered adequate, as long as they contain:

- the name and address of each party to the transaction
- the date of the transaction
- the name, quantity, and form of packaging of the ephedrine or pseudoephedrine product
- the method of transfer
- the type of identification used by the purchaser.

Reports

You must report to your local DEA office:

- Any unusual ephedrine, pseudoephedrine or phenylpropanolamine transaction -extraordinary quantity, uncommon method of payment or delivery, or any other
 suspicious circumstances
- Any unusual or excessive loss of ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories
- Any proposed transaction with a person DEA has requested in writing that you
 monitor (report before completing the sale).

Note: a transaction may not be completed with a person identified by DEA unless approved by DEA. Steps should be taken to prohibit sales to these persons.

Reports are to be made orally, whenever possible, to the local DEA office at the earliest opportunity and as much in advance of the sale as possible. A written report must then be filed within fifteen days of becoming aware of the above circumstances. Written reports must contain the same information as the required records, plus the telephone number of the other party, if possible, and a description of the circumstances leading you to make the report. Written reports should be made on the MCA Transaction Report (Form #8).

Identifying the Customer

The regulations require the wholesaler to "identify the other party" to the transaction. In general, an ongoing agreement with your customer, an account that you had for some time, and other such business relationships indicating you know your customer, should establish the kind of verification DEA is looking for. Credit applications and Dun and Bradstreet reports should be sufficient.

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MCA Recordkeeping Requirements

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Compliance Guidelines

- Verify that your customers are registered to purchase these products or are exempt from the registration requirement.
- Maintain required records (normal business records are sufficient if they contain the required information).
- Generate and review monthly the MCA dosage limit report (Exhibit R). Submit these reports to DEA.
- Report to DEA any unusual or excessive loss or disappearance of any ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories.
- Maintain a file consisting of any reports submitted to the DEA and the monthly Excessive Purchase Report.

Other Regulated Products

The requirements for ephedrine, pseudoephedrine and phenylpropanolamine also apply to other chemical products which wholesalers do not usually stock or stock and distribute in limited quantities. The recordkeeping and reporting requirements for these items, which are listed below, only apply when threshold limits set by the regulations are exceeded. A past review of sales history for the items that are stocked in certain Cardinal Distribution Centers indicated that typical distribution quantities do not come close to meeting these limits. However, division management should be aware of all regulated products in the event that DEA addresses this issue during an audit.

	Chemical	Threshold by base weight
	Anthranilic acid and its salts	30 kilograms
2	Benzyl cyanide	1 kilogram
3	Ergonovine and its salts	10 grams
4	Ergotamine and its salts	20 grams
5	N-Acetylanthranilic acid and its salts	40 kilograms
6	Piperidine and its salts	500 grams
7	3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms
8	Methylamine and its salts	I kilogram
9	Ethylamine and its salts	l kilogram
10	Propionic anhydride	l gram
11	Isosafrole	4 kilograms
12	Safrole	4 kilograms
13	Piperonal	4 kilograms
14	Hydriotic acid (57%)	1.7 kilograms (or 1 liter by volume)
5	Benzaldehyde	4 kilograms
16	Nitroethane	2.5 kilograms

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MCA Recordkeeping Requirements

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Impor	rts and Exports		
	Chemical	Threshold by volume	Threshold by weight
(A)	Acetic anhydride	250 gallons	1,023 kilograms
B)	Acetone	500 gallons	1,500 kilograms
C)	Benzyl chloride	N/A	4 kilograms
D)	Ethyl ether	500 gallons	1,364 kilograms
E)	Potassium permanganate	N/A	500 kilograms
F)	2-Butanone (MEK)	500 gallons	1,455 kilograms
G)	Toluene	500 gallons	1,591 kilograms

	Chemical	Threshold by volume	Threshold by weight
(A)	Acetic anhydride	250 gallons	1,023 kilograms
(B)	Acetone	50 gallons	150 kilograms
(C)	Benzyl chloride	N/A	1 kilograms
D)	Ethyl ether	50 gallons	135.8 kilograms
E)	Potassium permanganate	N/A	55 kilograms
F)	2-Butanone (MEK)	50 gallons	145 kilograms
G)	Toluene	50 gallons	159 kilograms

Note: The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

	Chemical	Threshold by volume	Threshold by weight
(A)	Hydrochloric acid	50 gallons	
(1)	Anydrous hydrochloric acid		27 kilograms
(B)	Sulfuric acid	50 gallons	

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MCA Recordkeeping Requirements

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REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory

To be taken on December 31

Initial Inventory

To be taken on the effective date that a

substance becomes reportable

Transaction Reporting

Quarterly, or, with DEA permission.

monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

• ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters Attn: ARCOS Unit 2401 Jefferson-Davis Highway Alexandria, VA 22301

• ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration ARCOS Unit P.O. Box 27273 Washington, D.C. 20038-7273

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Required Reports to DEA

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Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual ARCOS OCR Form - DEA Form 333 - (Form #9).

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10). Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on DEA Form 106 should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

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Required Reports to DEA

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FOIA Confidential Treatment Requested By Cardinal

Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11) in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on ARCOS OCR Form 333.

Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files DEA Form 41. Refer to DEA Correspondence 8/12/94 for additional information.

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. **Refer to DEA correspondence 11/17/97**.

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish written criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish reasonable criteria based upon customer purchasing patterns and then to adhere to them in monitoring orders. Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

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Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

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Required Reports to DEA

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CONFIDENTIAL

INTRODUCTION

Security is defined as the elements necessary to deter burglary or theft of controlled substances at a level of effectiveness that equals or exceeds federal regulations applicable to wholesaling. The elements include:

- Physical structures and barriers such as safes, vaults, cages, barricades, grilles, gates, fencing, locks and lighting;
- Electronic systems including burglary detection sensors and controls, emergency (holdup) signal devices, closed-circuit TV surveillance and recording equipment, access control systems, and communications devices; and
- Practices and procedures applicable to the installation, maintenance, inspection, testing and supervision of interrelated security devices and systems.

This section of the manual is provided to educate employees about DEA security requirements and to assist Division Management in evaluating compliance with these requirements.

In evaluating the overall effectiveness of a wholesaler's security against theft and diversion, DEA may consider, in addition to those security requirements previously discussed, any of the following factors:

- The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
- The quantity of controlled substances handled;
- The location of the premises and the relationship such location bears on security needs:
- The type of building construction comprising the facility and the general characteristics of the building or buildings;
- The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- The type of closures on vaults, safes, and secure enclosures;
- The adequacy of key control systems and/or combination lock control systems;
- The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

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- The adequacy of supervision over employees having access to manufacturing and storage areas;
- The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- The availability of local police protection or of the registrant's or applicant's security personnel, and;
- The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

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Physical and Procedural Security - Introduction

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PHYSICAL SECURITY - GENERAL WAREHOUSE

Management must insure that appropriate physical security measures are taken against the loss of company property and assets. The standards set forth in this section will assist in insuring reasonable protection of the company's assets.

Security of Design and Layout

In all cases of security planning, either for new construction or updating of current facilities, assistance should be requested from the Corporate Compliance Department.

It is suggested that management implement basic physical security designs from a Security In-Depth Approach.

In considering the design of a facility, use of all available resources in an efficient manner should be taken into consideration in order to achieve adequate protection for the facility. Emphasis should be placed on the operational requirement of the facility to determine the type and extent of physical security needed.

Protecting a drug warehouse in this day and age is a difficult task. Some of the factors to be taken into consideration when setting up an in-depth security protection system are:

- The exact function to be performed at that location
- The environment political economic legal terrain
- The vulnerability
- The area (geographic, neighborhood)
- The cost involved
- The possible future changes in the operation

The degree of protection should be predicated on what affect the loss would have on the operation and the relevant importance of the operation to the total business. Additionally, consideration should be given to the degree of susceptibility the operation has to outside threats. These threats are acts or conditions that may result in:

- Disruption of the facility
- Damage, loss or destruction of property
- Personal injury or loss of life
- Compromise of critical information

Threat severity depends on such variables as:

Type of facility

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- Function performed (distribution of drugs)
- Physical layout and construction
- Geographical location
- Stability of location
- Existing state of law and order
- Protection measures already in affect, if any

Perimeter Barriers

Perimeter barriers may be used to define the physical limits of a facility. They are used generally to restrict, channel or impede access. In addition, they offer two important benefits; create a psychological consideration and have a direct impact on the number of security posts that may be needed. The two major categories of barriers are natural and structural, the one most commonly used is fencing. When practical to do so, all facilities should be fenced. This action will provide a first line of defense against the criminal element.

- Fencing should be of the No. 9 gauge or heavier fabric. The mesh openings should not be larger than two inches. To prevent individuals from going under the fence, a cement apron not less than six inches thick can be installed under the fence. The top of the fence should contain an anti-climb overhang or barbed wire, installed at a 45 degree angle outward, consisting of three strands of barbed wire. In some instances, it may be desirable to employ an additional strand of razor ribbon which is interwoven between the strands of the barbed wire on the top of the fence.
- Gates, entrances and other openings in a perimeter barrier should be limited to the number necessary for efficient and safe operation of the distribution center.
- All fence lines should be cleared areas and be free from obstruction. The area should be cleared of weeds, rubbish, or other material capable of offering cover or assistance to an intruder attempting to climb, cut through, or tunnel under.
- Exterior doors may be an inviting entrance for an intruder because of convenience. The
 vulnerable points at the door are the frame, hinges, door panels and the lock.
- Doors should be installed so that the hinges are located on the inside. If this is not
 possible, the hinges should be installed so as to prevent their removal and the exterior
 pins should not be removable. The hinges that are on the exterior of the doors should
 be welded, brazed, or otherwise secured.
- Doors should be of metal or solid wood construction.
- Glass exterior doors should be equipped with decorative metal bars or be of the type of glass which resists breakage.
- Rolling overhead doors not controlled or locked by electric power should be protected by slide bolts on the bottom bar on the inside and padlocked when not in use.

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- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a deadbolt lock with at least a one-inch (1") throw. These deadbolt locks should be protected by a case-hardened steel sleeve. This sleeve should cover the deadbolt throw and any other locking mechanism (e.g. electronic strike) on the door.
- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a wide-angle peep-hole. This mechanism will give employees a view of anyone requesting entry into the distribution center from the outside. If there is any doubt about the person's identity, then that person should be informed to report to the front door of the distribution center.
- Employees at the distribution center should not be allowed to park within fifty feet (50') of either the shipping door(s) or the receiving dock. When parking is limited at the distribution center, then it should be a standard rule that employees that work in these areas do not park near their respective work areas.
- There should be absolutely no markings on the distribution center identifying it as a
 drug warehouse. This includes signs over both the shipping and receiving doors or
 decals associated with drug associations attached to the glass on the distribution center.
- Utility boxes which are located on the exterior of the distribution center should be equipped with a padlock. If the utility company requests it, they should be issued a key to this box.
- For distribution centers which warrant it, closed circuit television should be installed
 on the exterior of the distribution center. The monitors for these cameras should be
 placed in strategic locations throughout the distribution center. The Corporate
 Compliance Department should be contacted prior to application of closed circuit
 television cameras.
- Shrubbery, trees and bushes should be trimmed down so that they are not above window level at the distribution center. Any exterior design, such as brickwork, latticework, or an exterior ladder should be removed from the exterior of the distribution center. These elements provide direct access to the roof of the building.

Protective Lighting

This safeguard has considerable value as a deterrent to thieves and vandals or any unauthorized entry. It is an essential element of an In-Depth Security Program. Requirements for protective lighting at facilities will depend on the situation and the areas to be protected.

Each situation requires careful study in order to provide the best visibility that is practical for such security functions as prevention of illegal entry, detection of intruders, inspection of vehicles, and illumination for distribution center employees exiting at night.

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- Plan protective lighting to assure adequate illumination to discourage or detect attempts to penetrate an area, and reveal the presence of unauthorized persons within the area.
- Light sources should be located to insure that illumination is directed toward probable courses of intruders.
- Shadowed areas caused by structures near or adjacent to vital areas should be illuminated.
- Design should provide for overlapping light distribution.
- Exterior areas which should receive consideration are fenced perimeters, gate access areas, entrances to the distribution center, and any outside storage areas.
- Emergency power should be included for critical lighting; controls and switches should be locked.
- Lighting in unattended areas can be controlled by time clocks or light sensor equipment.
- The lighting at the distribution center should be checked by a member of the management staff at the distribution center on a routine, periodic basis. Lighting which is not operating properly or is out completely should be repaired immediately.

Locks and Key Control

Locks are the most generally utilized security device. The lock is most commonly used in protecting installations and activities, personnel, classified information, and company property. It should be noted that regardless of their quality or cost, locks should be considered delay devices only and not positive bars to entry. Locks, therefore, must be supplemented, where appropriate, with other security and protection devices and combined into the Security In-Depth Approach.

- The distribution center should have a Lock and Key Control System. It should be a standard practice at the distribution center that the exterior door locks, along with the cage day-gate, vault day-gate, and the combination to the vault be changed on an annual basis, or when an employee having access to the keys to these locks and/or the combination to the vault leaves the company's employ or is transferred to a new location.
- The key to the front door of the distribution center should **never** be the same as the key to the warehouse. The cleaning crew, alarm company, and the police department should <u>not</u> have a key to the distribution center.
- A Key Log (Form #12) should be maintained or a Key Receipt (Form #13) should be issued for each key distributed at the distribution center. A copy of the key receipt 12/1/95
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goes to 1) the employee; 2) the distribution center manager; and 3) a copy is placed in the employee's personnel file. If an employee is entrusted with a passcard, then that number should also be placed on the key receipt form. Additional Key Receipt forms may be obtained from the Corporate Compliance Department.

- Spare keys to the distribution center, cage, or the combination to the vault should be kept in a secured location at the distribution center. These keys should be kept on the person of the employee entrusted with their care, or they should be kept on a locked desk drawer or small locked cabinet.
- A spare key to the vault should be secured <u>inside</u> the vault in an inconspicuous location. This key should be utilized in case distribution center employees are placed in the vault during the course of a crime.
- Padlocks which are utilized at the distribution center should always be left in the locked position when not in use. The serial numbers on these padlocks should be removed.

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Physical Security

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STRUCTURAL SECURITY

Schedule II Controlled Substances (21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations (21 CFR 1301.72(b)) provide that Schedule III through V controlled substances must be secured as follows:

• In a cage located within the building on the premises meeting the specifications in 1301.72(b)(4)(ii-iv) and Section 1301.72 (b)(3)(ii)(a)(b), which read as follows:

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21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
 - (a) At least one inch in diameter;
 - (b) Set in concrete or installed with lag bolts that are pinned or brazed; and
- (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall
 be erected which reaches and is securely attached to the structural ceiling of the
 building. A lighter gauge mesh may be used for the ceilings of large enclosed areas
 if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b) (3)(ii)."

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:
- (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
- (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination
- The controlled substance section also provides:
 The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

Alternate: Where swinging cage doors are installed, hinges are properly secured.

Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

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Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b) provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization should be posted, in plain sight, in the secured area. An additional copy of the authorization letter should be retained by division management.

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

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ALARM SYSTEMS

The alarm system at the distribution center should be one which provides telephone line security. Of the phone lines leading into the distribution center are compromised or cut, then this action should result in an immediate alarm at the distribution center. The police should then be notified immediately.

Any opening more than ninety-six square inches on the exterior of the distribution center should be added to the alarm system. These openings include air vents, roof hatches, skylights, etc.

The alarm equipment surrounding the cage and vault should be walk-tested at least once a month. Any equipment failures should be corrected immediately. The Monthly Alarm Walk Test Report (Form #14) should be completed and filed or distributed accordingly.

Schedule II Controlled Substances

The vault at the distribution center should be on a separate alarm system. This should be a standalone system with the following minimum security requirements:

The walls or perimeter of the vault are equipped with an alarm that includes standby power sources. When unauthorized entry is attempted, the alarm transmits a signal over a supervised alarm transmission circuit directly to a central station protection company; a local or state police agency that has a legal duty to respond; a 24-hour control station operated by the registrant; or such other protection as the administrator may approve.

The door of the vault is equipped with contact switches, and the vault has one of the following:

Complete electrical lacing of the walls, floors and ceilings; sensitive ultrasonic, microwave or passive infrared equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the administrator.

Additional motion detectors should be positioned directly outside and along the approach to the vault. These motion detectors should be able to pick up anyone approaching the vault when the alarm is set.

If necessary, due to local conditions or other problems, hold-up buttons shall be placed at strategic points of entry to the perimeter area of the vault.

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Schedule III, IV, and V Controlled Substances

DEA regulations applicable to the security of Schedule III through V controlled substances state that the cage shall be equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administration may approve.

A cage is protected by motion sensing devices that are positioned or mounted outside (around) and over the cage to detect an intruder prior to an attempt to enter the cage area.

The cage door(s) is equipped with an alarm contact switch.

Alarm Related Security Procedures

The cage and vault alarm system is tested at least annually by the alarm contractors. At that time, the alarm contractor is required to perform a complete on-site inspection, test and adjustment of the entire alarm system and to replace any components, sensors or wiring that are defective. The alarm contractor confirms, in writing, the results of this inspection, certifying that the system at the time continues to meet the contractual obligations between the company and the alarm contractor and any applicable UL certification standards.

Division management conducts monthly tests of the vault door alarm contact switch as well as any motion sensing or capacitance devices used in conjunction with vault protection. A log is maintained showing the dates of the tests performed, any defects, the date the alarm company was advised of the defect, and the date the problem was corrected.

Such records are maintained on file for 24 months for review by any DEA agent.

Instructions to the alarm company provide that in response to alarm signals, trouble signals, loss of line security or open telephone circuits, the alarm company will promptly respond to the facility, contact the police, if required, and notify division management as designated on a letter of instruction provided by the wholesaler.

Upon notification by the alarm company of the receipt of a signal condition described above, the designated supervisor identifies the caller, confirms that alarm company guards have been dispatched and the police notified, and then proceeds to the premises.

Note: Return call verification to the alarm company should be made any time Cardinal personnel are requested to appear at the premises.

On arrival, the supervisor verifies the presence of the police and/or the alarm company personnel at the site or if such is not the case, continues in his/her vehicle to a safe telephone location where the supervisor calls the police and/or the alarm company to arrange for their coincidental arrival at the premises. In some instances, it may be necessary for the supervisor to proceed to the police station in the vicinity to request a safe escort to the site.

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If only alarm company personnel are present at the supervisor's time of arrival, their identity should be visually confirmed and a request made for the guard to radio his/her office to recall the police. The supervisor and the alarm company should remain outside the premises until the police arrive.

The supervisor should then unlock the entrance door, turn on designated lighting, admit the police and the alarm company personnel, relock the entry door, and then remain in the safest possible area until the police and the alarm company guards have completed their search of the premises.

When entering the premises area, the company supervisor or the alarm company guard should open alarm system protected areas that must be entered in order to search the premises and arrive at the controlled substances vault.

When a search is completed and it has been determined that there is no forced entry or other emergency condition, the company supervisor assists the alarm company guard in resetting the alarms that have been activated and turns off the lights. Both depart the premises through the point of entry in the company of the police and return to their respective stations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

If it is determined that an actual burglary attack has taken place, the police officers radio or telephone for additional officers and other assistance.

Additionally, the interior and exterior areas are searched thoroughly for hidden or fleeing intruders; damage, if any, to the vault is repaired; the alarm system is restored and reset; and appropriate surveillance is established to detect any hidden or returning criminal activity. In the event that the burglary is discovered in the absence of police at the scene, the supervisor immediately contacts them to report the crime and request their prompt assistance. In addition, the local DEA office is promptly notified and DEA Form 106 is prepared and filed in accordance with DEA regulations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

Note: Many states require that a report be submitted to the board of pharmacy or other agencies with enforcement jurisdictions.

If the controlled substance vault has been physically penetrated or forced open, the supervisor must remain at the premises in charge of the scene until the structure or door is restored to normal or the warehouse reopens on the next business day. This is required despite the restoration of the alarm system since a vulnerability to a hit-and-run burglary would exist until the "physical security" has been restored.

If, for any reason, the alarm system cannot be restored to full normal operation, the supervisor must see to it that the following steps are taken:

- The supervisor remains at the scene and requests assistance, if necessary, from other company supervisors;
- The alarm company guard or service personnel responding to the alarm are requested to stay at the premises until the alarm system has been repaired and restored; and
- If the alarm system still cannot be restored, then the supervisor secures the services of alarm company guards, off-duty police officers, contract security guards or other

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appropriate security forces to maintain watch on the premises until security against burglary or robbery can be fully restored.

Note: Under such circumstances, there is a vulnerability relating to the safety of the supervisor and others who may remain on duty at the premises. Precautions that should be taken include locking all perimeter doors and windows, requesting that the police return frequently on a patrol basis, and requiring that the supervisor remain in frequent telephone contact with another supervisor located outside the premises at a safe point. In some instances, commercial telephone circuits may be out of order. In such case, the use of portable radio equipment and cellular phones may be required together with procedures for two-way communication between supervisors and/or the alarm company central station and the police.

• When full security has been restored, division management should review the incident to evaluate the cause and any improper or unsafe actions taken by responding personnel, and revise security procedures where appropriate to provide a more effective and safer response to a similar incident. On the day following the restoration of service, the alarm company is required to have a service supervisor thoroughly test the entire system and certify that the alarm system has in fact been restored to its original condition.

Alarm Related Procedures for Police Connect Alarm System Supervision and Response

Alarm systems connected directly to a police station or municipal communications center that is manned on a 24-hour basis require essentially the same response from the supervisors assigned such duties. The variations in response conditions are as follows:

- On receipt of a phone call from the police, the supervisor contacted requests the
 name and identification number of the police officer calling. The supervisor then
 recalls the commercially listed number of the police agency and verifies the
 authenticity of the call prior to departing the safety of his/her residence.
- On arrival at the warehouse, the supervisor verifies the presence of a police officer or proceeds as previously instructed to again call the police to the scene prior to entering the premises.
- When search and entry of the premises are completed, the supervisor restores the alarm circuits and departs with the police officer.
- In the event that the alarm system cannot be restored, the supervisor contacts the 24-hour telephone number of the alarm company (if available) and requests a service man to respond immediately to the premises to repair, adjust or otherwise restore the alarm system. If feasible, the supervisor should request that the police officers remain at the scene until the alarm company service representative arrives.
- An Incident Report (Form #15) should be completed and sent to the Corporate Compliance Department.

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Alarm Systems

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ACCESS CONTROL

General Warehouse

It is the policy of Cardinal to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs should be posted on all warehouse entrances regarding limited access (Exhibit B).

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Division Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

"The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." (21 CFR 1301.72(d))

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Access Control

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Division management maintains an Access and Surveillance List (Form #16) of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list should be posted along with a "Restricted Area" (Exhibit C) sign on the door(s) of the vault and cage.

Temporary employees should never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system should include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees should keep passwords to themselves and periodically change them to prevent access by others. Access should be limited for inventory adjustments, customer licensing information and financial records.

Computer room access should be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

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Access Control

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PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter should be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures should be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. Refer to Drug Thefts/Losses within Required Reports to DEA. The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to 21 CFR 1301.74 (e) upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them.

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

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Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number
- National Drug Code

Quality Control

All controlled substance orders should be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package should be labeled with the name of the customer. There should be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

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Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form -DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor should be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo should remove the product from inventory. Proof of delivery should be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item. The Selected Item Audit Report (Exhibit I) gives all movement purchases, returns, sales and inventory adjustments for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances should only be made after a thorough research. Documentation should be kept on file to support any adjustments.

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Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center should be opened by at least two employees. These employees should meet at a safe, well-lighted, off-site location. The employees should then proceed to the distribution center and one employee should enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure should be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

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SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with 21 CFR 1301.90 and Cardinal's policy which requires all prospective employees to consent to a drug test and a criminal record check. Delivery Vehicle Security Rules (Form #17) are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

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Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do no indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules (Form #17) are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

<u>Durability</u> A seal must be strong enough to prevent accidental breakage during normal use.

<u>Design</u> The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

<u>Tamperproof</u> The seal should provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

<u>Individually Identifiable</u> Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

<u>Time of Application</u> Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

<u>Verification</u> Seal examination and verification at every stop such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log.

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Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a Will Call Log (Form #18) that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

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Shipping

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C. 1491 William Jones Company

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PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a Pre-Employment Waiver (Form #19) consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment should not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a Post-Employment Security Data Information Sheet (Form #20). The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the Test for Distribution Center Employees Handling Controlled Substances (Appendix B) as well as the Post-Employment Security Data Information Sheet. The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check should be performed prior to the distribution center manager assigning the employee to the controlled substance area.

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Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription or reporting to work or working under the influence of alcohol or a controlled substance without a medical prescription is strictly prohibited. If an employee requires medication which may affect their performance, they should notify their supervisor immediately. DEA regulations regarding this should be posted in the facility (Exhibit D).
- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.
- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.
- Protection of Company property is a responsibility all employees must share. Any employee
 discovering theft, loss, or malicious damage has an obligation to report the incident
 immediately to his supervisor.
- Fighting or instigating a fight with an employee, customer, or supplier while on Company
 property is strictly prohibited. No permanent personnel action will be taken until there is a
 complete investigation by Management.
- Tampering with or breaching Company security systems or policies is prohibited.
- Theft or unauthorized removal or use of Company or another employee's property is prohibited.
- Possession of firearms or illegal weapons on Company property is prohibited.
- Employees must use their own card entry access card, and access cards should not be loaned to other employees. Lost access cards should be reported to Management immediately.
- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.
- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.
- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the facility. Signs to this affect should be posted throughout the distribution center (Exhibit E). Random periodic inspections could serve as a deterrent to internal theft.

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- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.
- Visitor's entering the distribution center should be asked to sign in on a Visitor's Log (Form #21), indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor should wear a badge and must be escorted during their stay.
- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.
- Coats and pocketbooks are not allowed in the warehouse.
- Employees are to adhere to the posted access list for the cage and vault area.
- A Miscellaneous Security Log (Form #22) should be used to document any minor securityrelated incidents that occur but do not need to be explained in detail.

Security rules should be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled Violence Prevention Procedures (Exhibit G) should be posted in conspicuous locations throughout the distribution center. These procedures should be reviewed with distribution center employees on a routine, periodic basis. It is paramount that all employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

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- Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
- In the event of a robbery:
 - a. Offer no resistance.
 - b. Stay calm.
 - c. Be observant.

Driver security rules should be distributed to all drivers and a signature obtained to document receipt.

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INSPECTIONS OVERVIEW

Overview

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (the Controlled Substances Act") authorizes the Drug Enforcement Administration (DEA) to enforce provisions of the act as they apply to registered handlers of controlled substances. The stated DEA goal is "to significantly reduce the availability of licitly produced drugs used for illicit purposes in the United States."

The act establishes a comprehensive system to control the manufacture and distribution of controlled substances necessary for legitimate medical needs. Since the controlled substances in question include some of the most potent drugs known to man, the incentive to divert these drugs into the illicit market is great. Drug related deaths and injury statistics indicate that legally produced controlled substances account for a large percentage of drugs associated with drug abuse injuries reported by hospital emergency rooms. In fact, 15 of the top 20 controlled substances reported in hospital emergency room mentions were pharmaceuticals legally available in the United States market.

The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances and for investigating diversion of these substances into the illicit market. The Diversion Control Program prevents, detects, and investigates the diversion of controlled substances from legitimate channels, while at the same time ensuring an adequate and uninterrupted supply of controlled substances required to meet legitimate needs. To achieve this goal, DEA's diversion program uses programs designed to maximize the effect of criminal, civil and regulatory investigations and controls intended to limit the availability of diverted substances.

The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; an organized system of drug destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

These activities are designed to meet DEA's responsibilities under the Controlled Substances Act and to prevent the diversion of controlled substances from legitimate distribution channels. When violations are discovered, appropriate action (administrative, civil or criminal) will be considered.

As we move further into the 1990s, the pharmaceutical industry is facing an increasingly active enforcement and regulatory climate.

DEA registrants must be aware of this climate, and ensure that they are in full compliance with DEA requirements or take immediate corrective action before DEA investigates their facility.

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Inspections Overview

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Notice of Inspection

Cardinal Health recognizes the fact that federal and state regulatory agencies have explicit authority to inspect our premises and records.

Upon notice of a federal or state regulatory inspection, contact the Corporate Compliance Department immediately and advise to the nature of the visit, names of the officials and the agency they represent. The Department can be of assistance in helping to verify an individual's identification if the need arises.

Full cooperation must be given to the inspecting authorities. However, only persons authorized by division management may answer questions posed by the regulatory inspector. Inspections should be monitored closely by qualified Cardinal personnel, and a daily detailed written record in the inspection must be prepared.

Upon arrival of the investigators at the registered location, the manager, his/her designated alternate and the individual who has overall responsibility for controlled substances should meet with the investigators as soon as possible, review their credentials (a picture of the person on an official ID Card) and accept the DEA Notice of Inspection. Inspector(s) should be asked to sign the Visitor's Log and given a Visitor Badge to be worn at all times. A discussion should then be held regarding the purpose and extent of the investigation and the desire of management for a close-out discussion at the completion of the investigation. (21 CFR 1316.05)

If you are not sure that the individual requesting entry is a bona fide city, state, or federal official do not allow them to enter the distribution center. Request information as to whom they report (their immediate supervisor) and how (telephone number) you can verify their identification.

Note: Receptionist should not admit inspector(s) into facility or accept their credentials.

Authority of the DEA Investigator

21 USC 880 and 21 CFR 1316.03 allow DEA investigators to enter a registered location (controlled premises) upon stating their purpose and presenting credentials and a written notice of inspection or, if warranted, an administrative inspection warrant for the purpose of:

- Inspecting and copying records, reports and other documents required to be kept or made;
- Inspecting, within reasonable limits and in a reasonable manner, all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Controlled Substances Act;
- Conducting a physical inventory of all controlled substances on the premises;
- Collecting samples of controlled substances pursuant to DEA Form 84; and
- Checking records and information regarding the distribution and receipt of controlled substances by the registrant.

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Exclusion From Inspection

Unless consented to in writing by the registrant, no inspection authorized by 21 USC 880 and the implementing regulations should extend to:

- Financial data;
- Sales/receipt data other than shipping and receiving data; or
- Pricing data.

Entry to Premises

DEA officials will conduct the investigation. The officials have the right to enter the registered premises and conduct the investigation at reasonable times in a reasonable manner once they state their purpose, present their credentials and written notice of their inspection authority (DEA Form 82) to their responsible registrant official, and receive informed consent or present an administration inspection warrant.

An administration inspection warrant is not required if informed consent is obtained from the registrant. Whenever possible, the informed consent should consist of a written statement (DEA Form 82 with addendum—language found in Section 1316.08) signed by the registrant.

Investigation

An individual (preferably a responsible officer or employee) who is familiar with the DEA record keeping and reporting requirements and security in place at the facility always should accompany and monitor the investigators.

This individual should be prepared to:

- Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting the areas;
- Explain the operation/type of security, record keeping and reporting systems/procedures maintained;
- Assist the investigators;
- Verify the accuracy of the information the investigators obtain from inventories, sales and purchases documents and make a list of the records reviewed;
- Obtain copies for and retain copies of any documents the investigators request;
- Assure that information volunteered is clearly beneficial to the wholesaler;
- Assure no misrepresentations are given to the investigators;
- Note any suggestions or criticisms expressed by the investigators. Any violations discovered in this manner should be corrected immediately and documented; and
- Complete a daily detailed written record of inspection that includes the following:
 - any questions raised by the inspector,

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- any questions raised by the monitor.
- any requests made by the inspector,
- what the inspector was shown,
- a list of any records viewed or copied by the inspector,
- items inventoried and verification of the inspector's counts,
- any suggestions of criticisms expressed by the inspectors,
- complete a DEA Inspection Report (Form #23) and forward to Corporate Compliance Department.

Note: The registrant using this report and statements made by the investigator should reconstruct the investigation to verify any violations or, as is possible, reveal no violations.

All personnel are instructed not to read, acknowledge in any way, or sign any affidavit presented to any Company employee by an investigator.

Discussion with Management (Close Out)

This phase will be used by DEA to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by non-acceptance of the violations. Explain that Cardinal Health, Inc. employs a Director of Compliance and inquire if the results of the inspection warrants his presence at the exit interview. If yes, contact the Director of Compliance immediately. If the DEA intends to take further action, the registrant may or may not be informed of what courses of action are possible. The registrant will not be informed of the specific action to be recommended.

Note: DEA is not required to conduct a closing discussion at the completion of the investigation. If not initiated by the investigator, the registrant should request a closing discussion at the convenience of the investigator. If this fails, it is suggested that a request be made in writing to the investigator's supervisor, expressing the desire to meet and discuss the findings and any corrective action that may be required.

If a closing interview is held, the investigator may advise the registrant of any violative conditions. If the registrants cannot obtain a closing discussion, the report prepared by the employee(s) assigned to accompany the investigator during the investigation should be utilized to reconstruct the investigation and findings.

Once aware of any violations, the registrant should take the following initiatives in seeking and implementing corrective actions:

- Reconstruct the investigation and findings, using the same documents, facility review utilized by the investigators and the registrant's internal report.
- Take appropriate action to correct any violations or problems uncovered during the DEA investigation; and
- Convey to DEA the corrective action taken, what steps the registrant has taken to prevent future problems and inquire what further action the registrant should take.

It is suggested that if a registrant's investigation disagrees with the DEA investigation, they should contact DEA immediately and request a meeting to discuss the findings.

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DISTRIBUTOR ACCOUNTABILITY INVESTIGATIONS PROCEDURES

An investigation is divided into four phases: preparation, on-site, follow-up and past history. The information sought by the DEA during each phase is outlined below.

Preparation

Prior to inspecting a facility, the registrant files at the respective DEA location are reviewed; i.e., review of ARCOS reports, review of registration categories and schedules, etc.

On-Site Investigation

Initial Phase

The initial phase involves initial discussion, presentation of investigator credentials and notice of inspection (if a warrant is used, the registrant should consider the need for an attorney). The credentials and notice will be presented to that person who has managerial responsibility for operating the firm. The investigator should state the purpose and indicate the scope of the investigation.

Management at this time should request that the investigators advise them of any violations discovered during the investigation so that corrective action can be taken immediately. Management should state that they desire a closing discussion at the completion of the investigation.

Background Information

The DEA investigators will want to know the:

- Names, addresses, date of birth and social security numbers of corporate officers and/or owners of the registrant and identification of individuals responsible for record keeping and security;
- Number of employees and appropriate registration (federal, state and local); and
- Percentage of business dedicated to controlled substances.

They also will want to review reporting procedures regarding thefts, losses or destruction of controlled substances.

A completed copy of the DEA On-site Background Information Package (Form #28) can provide the DEA Inspectors with pertinent company information.

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Distributor Acountability Investigations Procedures

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Closing Inventory

The closing inventory is usually taken before or after business hours, so that no adjustments for transactions outside the accountability period are necessary. An accurate inventory is necessary and advantageous. All shipping, receiving and return areas, as well as other areas where controlled substances might be stored, should be checked.

A responsible employee of the registrant should verify the accuracy of the inventory and make a copy for the registrant's records.

Initial Inventory

An actual inventory taken by the registrant, an inventory from a previous DEA investigation or a computer inventory printout may be utilized if the registrant will attest to its accuracy.

Regardless of the inventory used, the required biennial inventory will be reviewed.

Receiving Records

Order forms will serve as the primary record of documenting the receipt of Schedule II controlled substances. They also will be reviewed for accuracy.

The power of attorney will be reviewed.

ARCOS reports and purchase invoices will be reviewed to verify accuracy of the order form transactions for Schedule II controlled substances and Schedule III narcotic controlled substances.

Receiving records which record supplier's name, address, and DEA number; name of controlled substance; strength; quantity received; and date of receipt for Schedule III through Schedule V will be reviewed. These records must be kept in a readily retrievable manner. The registrant will be required to attest to the accuracy of the records.

Sales Records

Order forms will serve as the primary record documenting the sale of Schedule II controlled substances. They also will be reviewed for accuracy.

Registration of customers will be verified.

A sampling of ARCOS records and customer sales records for Schedule II controlled substances and Schedule III narcotic controlled substances will be reviewed to verify shipments.

The quantity of Schedule III through Schedule V controlled substances distributed may be determined from a number of different types of records. The primary record is the distributor's sales invoice.

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Distributor Acountability Investigations Procedures

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Sales will include all dispositions from inventory, including documented and reported thefts, returns and destructions.

Credits and Returns

A review of credit memoranda will be made to determine that there was physical movement of controlled substances or credit.

Returned controlled substances will be inspected to verify that there is documentation showing returns, disposition by destruction or return to inventory.

Note: If the registrant has another record keeping system, such as the computerized Selected Item Audit Report which contains all required information and attests to its accuracy, these records may and should be used.

ARCOS

Reports will be verified by comparing them to other purchase and sales records.

Accountability

The initial inventory is combined with all receipts (including returns) of controlled substances and compared to the closing inventory plus sales, destructions, returns, reported thefts or losses accounted for by the registrant from its records.

Security

This evaluation will include:

- Review of location, crime classification, building construction, access restrictions and storage areas, including size and type of physical security systems in place;
- Evaluation of alarm systems and test;
- Review of security and procedures employed in shipping and receiving areas, picking areas, and packaging areas;
- Review of procedures for determining proper registration of customers;
- Review of frequency of alarm checks and procedures for key control, after hours entry, badge system and lock changing; and
- A review of the registrant's system for monitoring unusual and excessive orders.

Discussion with Management

This will be used to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by nonacceptance of the violations. If DEA's intention is to take further action,

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Distributor Acountability Investigations Procedures

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the registrant may be informed of courses of action possible, but not the specific action to be recommended.

Note: DEA is not required to conduct a closing discussion at the completion of the investigation. In this case, the registrant should request a closing discussion at the convenience of the investigator. If the request is not successful, it is suggested that the registrant send a written request to the investigator's supervisor, expressing the desire for a meeting to discuss any findings and corrective action which may be required.

Follow-Up Investigation

After the on-site portion of the investigation is completed, a verification of purchases and sales most likely will be performed. The extent of the verification will depend upon the nature of the investigation and discrepancies found. In addition, DEA may conduct file checks on all persons who are interviewed during the investigation.

History of Violations

The registrant's history if violations will be taken into consideration by DEA in determining the type of action to be levied against the registrant.

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Distributor Acountability Investigations Procedures

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VIOLATIONS

The DEA will take action against a registrant in all instances where an investigation reveals violations of the Controlled Substance Act and the implementing regulations. The Table of Offenses and Penalties (Exhibit H) summarizes these violations.

Administrative Actions

Revocation of Non-Practitioner Registration or Application Denial

DEA registration or application may be revoked, suspended or denied if at least one of the following conditions is present:

- The application for registration has been materially falsified;
- The registrant (owner, officer, controlling stockholder) has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
 - 1. Maintenance of effective controls against diversion,
 - 2. Compliance with applicable state and local law,
 - 3. Prior conviction record relating to controlled substances,
 - 4. Registrant's violative history,
 - 5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle controlled substances has been suspended, revoked or denied.

"No Automatic Renewal" of Registration

To prevent renewal of the registrant's registration, the DEA will place an administrative code on the registration.

This procedure is usually utilized to suspend approval of the renewal application when the investigation shows that the registrant has failed to maintain adequate controls against diversion and grounds for denial exist.

The registrant is authorized to continue operating on a day-to-day basis until final action is taken (voluntary surrender, denial of renewal application or removal of the administrative code).

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Violations

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Letter of Admonition

The letter of admonition advises the registrant of the violations found and documents these violations in written form. This allows for voluntary, corrective actions by the registrant and makes the violations a matter of record should the same violations be encountered at a later date.

Administrative Hearing

A hearing will be held when the severity of the violations and the registrant's attitude toward them render the letter of admonition ineffective. An administrative hearing provides DEA and the registrant with the opportunity to explain their respective views on the violations and to discuss the necessary corrective actions.

Order to Show Cause

An order to show cause may be issued to a registrant for denial, revocation or suspension of a DEA registration for one of the following factors:

- The application for registration has been materially falsified;
- The registrant has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
 - 1. Maintenance of effective controls against diversion,
 - 2. Compliance with applicable state and local law,
 - 3. Prior conviction record relating to controlled substances,
 - 4. Registrant's violative history,
 - 5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle con-trolled substances has been suspended, revoked or denied.

During a show cause hearing, the registrant has the opportunity to explain why the registration should not be suspended or revoked.

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Violations

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Civil or Criminal Prosecution

The use of civil or criminal prosecution will be determined by the severity of the violations found during the investigation and discussions with DEA management and the assistant U.S. attorney.

The determination between civil and criminal prosecution is made based upon the registrant and/or person knowingly or intentionally committing the violation(s).

Civil penalties are assessed at \$10,000 per violation.

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Violations

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Buick Reference Index System

c 1991 Wilson James Commany

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Guide to Handling **ARCOS Transactions**

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GUIDE TO HANDLING ARCOS TRANSACTIONS

Introduction

The Automation of Reports and Consolidated Orders System (ARCOS) was developed by the DEA to report inventories of selected controlled substances and increases and decreases to these inventories. The selected controlled substances are Class II and III narcotics.

Transactions can be reported electronically via tape or diskette, or manually using ARCOS Form 333. In most divisions, a majority of the ARCOS records are created automatically during the receiving, invoicing and crediting processes. Other records must be created by manually entering the data into the ARCOS Maintenance Menu.

A report of all ARCOS transactions generated by the system is available for review. Depending on the system, this may be daily or monthly. Prior to submission to ARCOS, erroneous transactions can be changed or corrected using the ARCOS Maintenance Menu.

Distributors are required to take an annual inventory of each reportable controlled substance on December 31st and file it with ARCOS no later then January 15th of the following year. Increases and decreases in the inventory of each reportable controlled substance must be reported on a monthly basis and filed with ARCOS no later than the 15th of the month following the end of the reporting period.

For automated reporters, a tape of these transactions is sent to ARCOS, with a hardcopy report maintained at the division for two years. This report is useful when researching errors identified by ARCOS as it contains additional information, including item number and description, invoice number and customer or vendor number. For manual reporters, hand-written transactions are submitted to ARCOS on Form 333. One copy of the form is maintained at the division for two years.

ARCOS 'reads' the tape and generates a report entitled "ARCOS Daily Transactions Processing Error Report." The report will either acknowledge that no errors were found, or will list the transaction records in error, with the error code, description of the error and a correction number. Corrections must be made and the transactions resubmitted. Error reports should be maintained at the division for two years.

All media submitted to ARCOS should have a barcode label attached. Submissions should be made as described below:

ARCOS reports sents via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

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ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration ARCOS Unit P.O. Box 27273 Washington, D.C. 20038-7273

Inquiries can be made to the ARCOS Unit at (202) 307-8600.

What to do before sending a report to ARCOS

The Distrack system has a daily report of ARCOS transactions, while the HP generates the report at month-end. Each system has the ability to make changes, additions and deletions prior to the submission of the transactions to ARCOS. Instructions can be found in the ARCOS Maintenance Section.

In the review process, look for

- DEA numbers that do not fit the typical format (2 letters followed by 7 numbers),
- blank numbers that do not fit the typical format (9 digit number),
- items that are not ARCOS reportable,
- quantities that appear to be excessive or out of the ordinary, and
- inventory adjustments.

Keep in mind that the only transactions that need to be reported to DEA are those that document an actual transfer of product. Records created by inventory adjustments when the product is moved from the live inventory to the morgue inventory do not represent a transfer of product and should be deleted. Credit and rebills for contract/chargeback purposes and dropship billings are two more examples of financial transactions that do not represent the actual transfer of product.

If changes need to be made to an Associate's DEA registration number, the modification should also be made in the Customer or Vendor Master File so that future transactions do not contain the same error.

ARCOS reportable items that are documented as lost-in-transit or stolen on DEA Form 106 or as destroyed on DEA Form 41, need to be reported as transactions to ARCOS. Since forms to the DEA are submitted manually, ARCOS records are not generated by the system and need to be created.

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For an item lost-in-transit,

- use the date of the sale,
- the NDC and quantity of the item,
- the associate DEA number as the original sale record,
- a transaction code of X.

For a theft,

- report the date the theft occurred or was identified,
- the NDC and quantity of the item,
- a transaction code of T.
- The associate DEA number should be left blank.

For a destruction of a controlled substance (destroyed at your registered location),

- use the date the destruction occurred,
- the NDC and quantity of the item,
- a transaction code of Y
- the associate DEA number for the regional DEA office.

Product sent to a third-party for destruction are documented as a sale to the company. ARCOS records should be created through the invoicing process using transaction code S. If these activities occurred during a previous month, they should be reported as late transactions using the I code in the Action Indicator column.

ARCOS reportable items that are returned from an unknown source need to be documented as an addition to the inventory. This record is not generated by the system and needs to be created.

For an unsolicited return,

- use the date the product was received at the facility,
- the NDC and quantity of the item,
- a transaction code of V,
- the associate DEA number of UNKNOWN

The following are some sample lines from a report from the Distrack system., with a summary of what it means.

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THE MUNSTER COMPANY
ARCOS TRANSACTION EDIT REPORT
DAILY TRANSACTIONS CALLED FOR BY SYC593 - END OF DAY PROCESSING

	C 0 9 9 8
	INVOICE NUMBER 0000000 0000000 4207012
	SHIP- ACCT# 000000 000000 381914
SING	BILL 2TY ACCT 1 12 000000 1 000000 2 381914
CES	
ARLDS IKANSACTION EDIT REPORT DAILY TRANSACTIONS CALLED FOR BY SYC591 - END OF DAY PROCESSING PERIOD ENDING 3/19/98	CORRECTION D NUMBER C (
S IKANSACTION EDIT REP CALLED FOR BY SYC593 - PERIOD ENDING 3/19/98	A BLANK FORM NO. 973632612
ARLUS IKANSACTION EDIT REFORT NS CALLED FOR BY SYC593 - END PERIOD ENDING 3/19/98	ASSOC. ASSOC. DEA 1D NO. REG. NO. 5570 PT0226820 UNKNOWN 381914 AB3010763
AKK NSACTIONS	ASSOC. ID NO. 5570 381914
DAILY TRAI	DESCRIPTION MS CONTIN CR 100MG 25UD PFC C2 NEMBUTAL SOD 18.2MG 480ML C3 PRQTUSS 120ML GRAPE HOR C3
	TTEM NUMBER NDC NUMBER 18 1084 00034-0517-25 104334 00074-3142-01 148976 59630-0100-04
	NUME NUME
	DATE 3/19/1 3/19/1 3/19/1
	ANSACTION INT. CDE 6499 P 6503 S 6650 S
	TRANSACTION————————————————————————————————————

PO# 49623 00000

MFG# 05570 05000 00000

INVOICE DATE OVOOVOO OVOOVOO 98/03/19

Field Name	Description	Definition	Function
YYMM	year and month	4 digit code to identify the year and month of the reporting period	reported to ARCOS to identify the reporting period
IDENT	transaction identifier	sequential number assigned by the reporting registrant to each transaction record	reported to ARCOS to identify the transaction
CDE	transaction code	single-character field which identifies each specific ARCOS-reportable activity. The entire list of available codes is on the next page.	reported to ARCOS to identify the activity
DATE	transaction date	the actual date on which the activity occurred	reported to ARCOS to identify the date of the activity
ITEM NUMBER	item number	number assigned by the company to a particular SKU	used by the division for research and identification purposes
NDC NUMBER	National Drug Code number	11-character code that identifies controlled substance products	reported to ARCOS to identify the item
DESCRIPTION	item description	description of the item including size, strength, and finished form	used by the division for research and identification purposes
ASSOC. ID NO.	associate identification number	number assigned by the company to the vendor or customer participating in the transaction	used by the division for research and identification purposes
ASSOC. DEA REG. NO.	associate DEA registration number	9-character field identifying the customer or supplier with which the transaction took place	reported to ARCOS to identify the other party in the transaction
BLANK FORM NO.	narcotic order form (DEA 222) number	9-character field for the number of the order form	reported to ARCOS for CII items
CORRECTION NUMBER	correction number	unique sequential number assigned by ARCOS to an erroneous transaction	reported to ARCOS for reprocessing a corrected transaction
DC	action indicator (formerly the delete indicator)	a single character field which initiates three different ARCOS data base operations	reported to ARCOS when deleting or revising previously submitted and accepted transactions, or when inserting unreported transactions from previous months.

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Field Name	Description	Definition	Function
QTY	quantity	numeric field containing the number of packages, weight, or volume being reported	reported to ARCOS to identify the quantity
BILL – ACCT #	Bill-to account number	customer number assigned by the company to the account that was invoiced for the product(s) in this transaction	used by the division for research and identification purposes
SHIP – ACCT #	Ship-to account number	customer number assigned by the company to the account that was delivered the product(s) in this transaction	used by the division for research and identification purposes
INVOICE NUMBER	invoice number	the number assigned to the invoice that reflects the sale to the customer	used by the division for research and identification purposes
INVOICE DATE	invoice date	the date the invoice was created. Usually matches the transaction date.	used by the division for research and identification purposes
MFG#	vendor number	number assigned to the vendor from whom the product was purchased	used by the division for research and identification purposes
PO#	purchase order number	number assigned to the order under which the product was purchased	used by the division for research and identification purposes
ADJ	inventory adjustment code	the code assigned to the adjustment to indicate the disposition of the inventory	used by the division for research and identification purposes
C/M#	credit memo number	the number assigned to the credit memo that reflects the return of the product from the customer	used by the division for research and identification purposes
SRC	source	identifies where the information came from that created the transaction record	used by the division for research and identification purposes

TRANSACTION CODES

(FROM PAGE 5-6 OF THE ARCOS REGISTRANT HANDBOOK)

INVENTORY TRANSACTION CODES

- 1 SCHEDULE CHANGE INVENTORY
- 3 YEAR-END INVENTORY
- 4 YEAR-END IN-PROCESS INVENTORY (MANUFACTURERS ONLY)
- 5 SPECIAL INVENTORY
- 8 NO YEAR-END INVENTORY

ACQUISITION TRANSACTION CODES (INCREASES TO INVENTORY)

- P PURCHASE OR RECEIPT
- R RETURN
- V UNSOLICITED RETURN
- W RECOVERED WASTE (MANUFACTURERS ONLY)
- M MANUFACTURED (MANUFACTURERS ONLY)
- G GOVERNMENT SUPPLIED
- L REVERSING (MANUFACTURERS ONLY)
- J RETURN OF SAMPLE TO INVENTORY (MANUFACTURERS ONLY)

DISPOSITION TRANSACTION CODES (DECREASES TO INVENTORY)

- S SALE, DISPOSITION, OR TRANSFER
- Y DESTROYED
- T THEFT
- N NONRECOVERABLE WASTE (MANUFACTURERS ONLY)
- U USED IN PRODUCTION (MANUFACTURERS ONLY)
- Z RECEIPT BY GOVERNMENT (SEIZURES, SAMPLES, ETC.)
- Q SAMPLING (MANUFACTURERS ONLY)
- K USED ON PREPARATIONS (MANUFACTURERS ONLY)

MISCELLANEOUS TRANSACTION CODES

- F REORDER DEA-333 FORMS
- X LOST IN TRANSIT
- 7 NO ARCOS ACTIVITY FOR THE CURRENT REPORTING PERIOD

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What To Do When A Report Is Received From ARCOS:

- 1. Place the ARCOS template over the error report to separate the columns of information.
- Identify the time period of the errors.
- 3. Retrieve the monthly report for that time period, to be used as reference.
- Review the error code and the necessary correction action.
- 5. Determine if the error needs to be resubmitted. (Is it an ARCOS reportable item? Does the record reflect an actual transfer of product?)
- 6. Research any information pertinent to the type of error (invoice, receiver, credit memo, narcotic blank, etc.)
- 7. Create correction transactions in the ARCOS Maintenance Menu of the computer system. These transactions should be made in the current month's tape and not in the month of the original submission.
- 8. Make any necessary changes to the customer/vendor file or item file that could prevent future errors.

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EDIT ERRORS REPORT

DRUG ENFORCEMENT ADMINISTRATION DEPARTMENT OF JUSTICE

DAILY TRANSACTIONS PROCESSING ARCOS-2

ERROR REPORT

TRANSYLVANIA, PA 66613 1313 MOCKINGBIRD LANE THE MUNSTER COMPANY

ERRORS FOR CONTROL RECORD == > RM1313666*043098M

E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION. RM1313666S 5045800340500000192 RD0104959980475707042898000010200009804011749 CORRECTION NUMBER: 00000102

E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER RM1313666P 0000802580100000020 PA303798296215675504079800001030009804012347 CORRECTION NUMBER: 00000103

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Errors for Control Record

SUBMITTING REGISTRANT NUMBER RM1313666

ASTERISK

043098

LAST DATE OF THE REPORTING PERIOD REPORT MEDIA (T=TAPE)

REPORTING FREQUENCY (M = MONTHLY)

LINE 1

REPORTING REGISTRANT NUMBER (DIVISION) RM1313666

TRANSACTION CODE

NATIONAL DRUG CODE (11 DIGITS) 50458003405

QUANTITY (8 DIGITS) RD0104959 00000192

ASSOCIATE REGISTRATION NUMBER (CUSTOMER OR VENDOR)

DEA ORDER FORM NUMBER (BLANK NUMBER, 9 DIGITS)

TRANSACTION DATE 980475707

CORRECTION NUMBER

00000102 00009804

042898

YEAR/MONTH OF REPORT

TRANSACTION IDENTIFIER 011749

LINE 2

ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA RESGISTRANT NUMBER

LINE 3

CORRECTION NUMBER: 00000102

ERROR CODES

(FROM PAGE 7-5 OF THE ARCOS REGISTRANT HANDBOOK)

- E01 REPORTING REGISTRANT NUMBER DOESN'T MATCH THE ONE ON THE CONTROL RECORD
- E06 DELETE INDICATOR FIELD MUST BE BLANK OR MUST BE THE LETTERS "A", "D", OR "I"
- E07 DELETE INDICATOR FIELD MUST BE BLANK IF A CORRECTION NUMBER IS PRESENT
- E12 TRANSACTION DATE CONTAINS AN INVALID MONTH AND/OR AN INVALID DAY
- E13 TRANSACTION DATE MUST BE THE LAST DAY OF THE REPORT MONTH OR QUARTER
- E14 TRANSACTION CODE REQUIRED A YEAR-END DATE IN THE TRANSACTION DATE FIELD
- E15 TRANSACTION DATE IS LATER THAN THE RUN DATE OF THE ARCOS 2 EDIT PROGRAM
- E16 TRANSACTION DATE IS NOT WITHIN THE REPORTING REGISTRANTS REPORT PERIOD
- E17 TRANSACTION DATE ISN'T WITHIN THE 2 YEAR DATE RANGE OF THE ARCOS SYSTEM
- E21 CORRECTION NUMBER ENTERED IN INVALID. IT MUST BE NUMERIC
- E22 CORRECTION NUMBER IS NOT IN THE ERROR FILE
- E25 THE ARCOS EDIT STILL FOUND ERRORS ON THE CORRECTION TRANSACTION
- E28 DATA ENTERED IN THE QUANTITY FIELD IS INVALID. IT MUST BE NUMERIC.
- E31 THE UNIT VALUE ENTERED CANNOT BE USED WITH THE ENTERED NDC NUMBER
- E32 UNIT VALUE MUST BE BLANK, "D", "K", "1", "2", "3", "4", "5", "6"
- E35 STRENGTH MUST BE BLANK FOR BULK FINISHED OR 0001 TO 1000 FOR BULK RAW
- E36 STRENGTH IN INVALID. STRENGTH MUST BE BLANK OR NUMERIC
- E40 TRANSACTION CODE IS INVALID. SEE THE ARCOS MANUAL FOR VALID CODES.
- E41 TRANSACTION CODE IS RESERVED FOR DRUG MANUFACTURERS ONLY
- E42 TRANSACTION CODE REQUIRES ASSOCIATE REGISTRANT NUMBER TO BE BLANK
- E43 ASSOCIATE REGISTRANT NUMBER REQUIRES TRANSACTION CODE "Y", OR "G", OR "Z"
- E44 TRANSACTION CODE CONFLICTS WITH THE NDC NUMBER'S CSA SCHEDULE
- E45 TRANSACTION CODE REQUIRES AN ASSOCIATE REGISTRANT NUMBER ENTRY
- E46 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR TRANSACTION CODE "Y/G/Z"
- E47 ASSOCIATE REGISTRANT NUMBER CAN'T EQUAL REPORTING REGISTRANT NUMBER
- E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
- E49 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR THE TRANSACTION CODE
- E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED
- E53 THE ORDER FORM NUMBER IS REQUIRED FOR SCHEDULE 1 & 2 DRUGS
- E60 TRANSACTION CODE 1 AN INVENTORY RECORD ALREADY EXISTS
- E61 TRANSACTION CODE 3 OR 8 YEAR-END INVENTORY AMOUNT ALREADY EXISTS
- E75 THE NDC NUMBER IS INVALID, IT CONTAINS ONE OR MORE SPACES
- E76 THE NDC NUMBER IS NOT IN THE DRUG FILE
- E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION

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ARCOS Transaction Maintenance/AS400

Through the modified ARCOS Transaction Maintenance Menu, changes can be made not only to transactions from the current month, but also transactions to previous months. All of the maintenance must be done in the current reporting period to ensure that changes are added to the current month's tape.

Since transactions can now be from a variety of months (previous or current), the transaction ID will consist of the year/month (YYMM) and sequence number (Seq), as shown on the far left of each transaction.

Screen 1

From the ARCOS File Maintenance Menu, you must select the file type and enter the report reference date, as well as an access path. The file type can either be Monthly (M), Annual (A), or Special (S). A majority of the time, this selection will be M. The report reference date is the last date of the reporting period you have selected. For example, if you want to look at the records for May 1999, then you would enter M and 05311999. Through your selection of an access path, you make the determination of how the transactions are sorted. Entering a 'starting at' value can help to limit your search, but is not required. By leaving that field blank, the search will begin with the lowest value of your selected access path. The options for access path are:

- 1 = Corporate Item Number
- 2 = Blank Number
- 3 = NDC Number
- 4 = Customer Number
- 5 = Vendor Number
- 6 = DEA Number
- 7 = Sequence Number

Screen 2

After selecting the file type, the reference date, the access path and pressing enter, the next screen is displayed. The columns appearing on the screen are:

Sel = select transaction to update

Seq # = transaction ID

Trans Date = transaction date

Cd = transaction code

Dc = action indicator (only used for late, adjusted, and deleted transactions)

Cst/Vnd = customer or vendor number, depending on which access path was chosen

NDC/Item # = NDC or item number, depending on which access path was chosen

Quantity = transaction quantity

ASS Reg # = Associate registration number (DEA number of the other party involved in this transaction)

Blank # = order form number (required for CII transactions only)

If you choose a 'starting at' value in Screen 1, that equals a valid value for that access path, then that value will be highlighted in all of the transactions where it is included.

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You can scroll through transactions with a higher value for the access path, but in order to view transactions with a lower value, you must enter another value into the 'start at' field at the top of the screen and press F8. This 'start at' value is associated with the access path code selected on Screen 1. To select an alternative access path, press F12 to return to Screen 1.

To make a change to a transaction, enter '2' in the 'Sel' column and press enter. This will display the Change/Delete Current window. Changes can be made to any fields that are underlined. After completing the changes, press 'enter' and the transaction will be verified for accuracy and will be updated in the file. This function can be used for any transaction in the current batch including the current month's transactions, as well as any added, late or corrected transactions that have been entered.

To delete a transaction, enter '4' in the 'Sel' column and press 'enter'. This will display the Change/Delete Current window. No information can be entered into this pop-up window. Press <enter> to accept the delete. This function can be performed for any transaction that is displayed in the current batch that is not already deleted, this includes the current month's transactions, as well as any added, late or corrected transactions that have been entered. Deleted transactions will be displayed with an 'X' in the Dc column.

To add (current month) transactions, press (F6). This will display the Add Transaction pop-up window will appear requesting the required information. After completing the window, press <enter> and the transaction will be checked for accuracy and a transaction ID will be assigned. This add function can only be used for transactions that have occurred in the current month. Adding transactions from previous months is done using F14.

To add late (previous months) transactions, press (F14). This will display the Late Transaction popup window will appear requesting the required information. You must assign a transaction ID that includes the YYMM of the transaction and an original sequence number. The YYMM must be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Late transactions will be noted with an 'I' in the Dc column. This function can only be used for transactions that have occurred in previous months.

To add corrected (DEA specified) transactions, press (F15). This will display the Correction Transaction pop-up window will appear requesting the required information. These transactions are identified on the ARCOS-2 Error Report. The correction transaction record must contain 1) all the fields that were correct on the original submission including the original transaction identifier, 2) the corrected field(s), and 3) the correction number. The YYMM must be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Corrected transactions will be noted with a correction number under the Corr# column. This function can only be used for transactions that have been identified as errors by the DEA and must not have occurred in the current month.

To adjust (previous months) transactions, press (F20) This will display the Adjustment, Deletion pop-up window will appear requesting the required information. This is to correct mistakes on previously submitted transactions. Once these are identified, wait until the error report is received from ARCOS. If the transaction appears on the error report, a correction must be made using F15. If the transaction does not appear on the error report and was accepted by ARCOS, an adjustment must be made using F20. The first record created will be coded 'D' in the Dc column. You will then be

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prompted to adjust the transaction to reflect correct information. The second record will be coded 'A' in the Dc column.

To delete (previous months) transactions, press (F21) This will display the Delete, Previous pop-up window will appear requesting the required information. This is to delete transactions that were previously submitted but should not have been. The record will be coded D in the Dc column.

To unfold the screen, press (F10). This will expand a single transaction to two lines and include the customer name and the item description.

To select all transactions that meet a specified value in an access path, press (F7). This will put a '2' in the 'Sel' column. If the transactions span for more than one page, you must page forward to the last page of the highlighted transactions to select all of these transactions. If you press F7 without first paging forward, you will only select the specified transactions from the first page.

<u>To mass update</u>, <u>press (F5)</u>. This will display the Mass Change pop-up window. From this window you have the option to change the NDC, DEA number or Blank number from the first transaction you selected to another value. It is recommended that mass changes only be made to the field that was selected in the access path.

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ARCOS File Maintenance - HP

Overview

In General:

The ARCOS File Maintenance screen allows the user to enter ARCOS File corrections. The screen was developed to replace the manual submission of corrections on ARCOS FORM 333 which the DEA will no longer accept from registrants who submit monthly reports electronically.

With the ARCOS file maintenance screen you have the ability to 1) make changes, additions and deletions to transactions prior to submission to ARCOS, 2) make adjustments, additions and deletions to transactions after acceptance by ARCOS, and 3) make corrections to transactions rejected by ARCOS.

Detailed Procedures

The ARCOS File Maintenance Screen is located on the **DEAMENUB**. To access **DEAMENUB**, log on to the live account and enter the following at the prompt: **MENU DEAMENUB**

Select option #11, ARCOS File Maintenance. This will take you to the ARCOS File Maintenance screen.

Note: Previous knowledge regarding the use of QUICK screens is needed to proceed with the following procedures.

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HODE:F ACTION:				DEA : RW0191318			
	ARCOS TRANSACTION MAINTENANCE						
	<u>Trans∘No.</u>	Date Cd	Dc	Order Form	H.D.C. No.		Assoc Reg# Correct#
01 02	1	11/01/96 S	_	<u>960224487</u>	00024027402	3	AN1471515
	2	11/01/96 S	_		00172564370	1	AM1471515
03	3	11/01/96 S	_	<u>960224488</u>	00074113403	10	AM1471515
04 05	4	11/01/96 S	_		00044072802	1	BB3984413
	5	<u>11/01/96</u> S	X		00785635001	1	BA3885160
06 07	6	11/01/96 S			00044072703	1	AT9562023
0,7	7	11/01/96 S	_		00044072803	1	AT9562023
08	8	11/01/96 S	_		60432045716	1	AT9562023
0,9	9	11/01/96 S	_		51079042099		BC3621047
1.0	10	11/01/96 S	_		50752029205	1	B\$4696590
1.1	11	11/01/96 S	_		51079042020	1	AH2103454
1,2	12	11/01/96 S	_		50474090201	1	BK3045211
1.3	13	11/01/96 5	_		50474090760	2	A\$3310315
14	14	11/01/96 S	_		50474090260	22	BN0963795
	15	11/01/96 S	D.	<u>961420472</u>	00008072901		AM5706861



This is a standard QUICK screen which allows the user to enter information needed tocorrect ARCOS transactions.

The Screen starts in find mode. The Screen will request the Trans ID to find or the user may hit enter to scan the file.

To change transactions

HODELE LATTON

Changes to transactions may be made using the Find/Change command (F2). Once a transaction has been selected either by transaction identifier or by line number, the date field is erased for change. If no change is required, press <enter> and the next field will be erased and the date will reappear. Continue this process through the entire line, making change(s) where needed. When completed with the line, press F6 to update the file. The change function can be used for any transactions in the current batch including the current months transactions, as well as any transactions added from previous months.

To add (current month) transactions

Transactions for the current month can be added using the Add Trans Curr Mo command (F4). The system will assign the next available transaction number. You will be required to add the rest of the information, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will only accept a date within the current month. To add a transaction from a previous month, use F5.

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To add late (previous months) transactions

Transactions for previous months can be added using the Add Trans Prev Mo command (F5). You will be required to assign the transaction number using the next sequential number for that previous months batch. You will also be required to add the rest of the information for that transaction, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will require that the transaction date be from a previous month.

To delete transactions

Transactions from the current month can be deleted using the Delete Trans command (F7). You will be required to identify the transaction by transaction identifier or line number. The transaction will be coded with an 'X' and will be excluded from the tape. You must press F6 to update the file.

To delete (previous months) transactions

Transactions from previous months can be deleted by using a two step process of adding a previous months transaction and changing the code. First, add a transaction from a previous month using F5, keying in all of the required fields, pressing <enter> to tab through the fields. When the record is complete, you have the option of updating or changing it. To change the record, type the line number of the transaction (1) in the 'action' field, then change the 'I' in the Dc column to 'D'. Press F6 to update the file.

To adjust (previous months) transactions

Transactions from previous months can be adjusted by using a deletion from a previous month, in combination with a previous month add and a change of the code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. When the record is complete, change the code in the Dc column from 'I' to 'D'. Press F6 to update the file. A second transaction then needs to be added, containing all the fields that were correct on the original submission including the original transaction identifier, the corrected fields, and the correction number. When the record is complete, change the code in the DC column from 'I' to 'A'. Press F6 to update the file.

To add corrected (DEA specified) transactions

Transactions for correction can be done using a previous month add, including a correction number, then deleting the 'I' code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. Remember to include the correction number assigned to the transaction on the ARCOS Error Report. When the record is complete, remove the code in the Dc column. Press F6 to update the file.

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Screen Definitions

Field Name	Field Description		
Trans No.	The ARCOS Transaction Identifier.		
Date	The transaction date, format of MMDDYY. Do not enter slashes the screen with auto format the field.		
Cd	Transaction Code. When in this field use Function key <f1> "HELP" for a list of acceptable transaction codes.</f1>		
Dc	Delete Indicator. This field is used to mark ARCOS transactions for delete. When in this field use Function key <f1> "HELP" for a list of acceptable delete codes.</f1>		
Order Form	The Order Form Number		
N.D.C. No.	The National Drug Code number.		
Quantity	The Quantity.		
Assoc Reg#	The Associated DEA Registration Number.		
Correct #	The ARCOS Correction Identifier.		

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Screen Definitions

Function K	ey Label	Function Key Description
F1	HELP	This will give Help on the screen when used in the Action Box and will give help for a specific field when used in that field.
F2 .	Find / Change	This is used to find transaction by a Trans ID or to scan the file. After finding a transaction, enter the line number of the transaction to modify the data in a field.
F3	Find By Date	This function key will allow the user to retrieve all the transactions for a specific date.
F4	AddTrans Curr Mo.	This will allow the user to add a transaction for the current month.
F5	AddTrans Prev Mo.	The will allow the user to add a transaction for a prior month.
F6	Update	After changing, adding or deleting any transactions this function key MUST be used to permanently save the transaction.
F7	Delete Trans	This function key is used to mark a transaction for delete.
F8	Exit	This key will allow the user to exit from the screen.

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DEA COMPLIANCE MANUAL

APPENDIX B

Test and Training Manual for Distribution Center Employees Handling Controlled Substances

TRAINING MANUAL FOR EMPLOYEES HANDLING CONTROLLED SUBSTANCES

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INTRODUCTION

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotic and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drug and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Protection Control Act of 1970 (the "Controlled Substance Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The trust of this Controlled Substance Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- record keeping requirements;
- manufacturing quotas;
- distribution restriction;
- limitations on imports and exports;
- conditions of storage of drugs;
- · reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable up to 15 years imprisonment and \$10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

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The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances into the illegal market. The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; and organized system of destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

This manual is intended as a resource to the Controlled Substance Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has and tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs Part 1300 to End – available from:

Superintendent of Documents U.S. Government Printing Office Washington, D.C. 20402 (202) 783-3238

ARCOS Reporting Manual - available from:

United States Department of Justice Drug Enforcement Administration ARCOS Unit, P.O. Box 27273 Central Station Washington, D.C. 20038-7273 (202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

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INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory. Refer to Procedural Security for additional information on the Physical Verification of Controlled Substances.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Cardinal Health has received authorized from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the Drug Enforcement Administration by January 15th of the following year.

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Periodic (21 CFR 1304.11)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. (21 CFR 1304.11 (d))

Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.

Retention of Inventory Records. The record must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. (21 CFR 1304.04)

Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

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DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

<u>Prefix.</u> 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). (Refer to DEA Correspondence 8/25/93). The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

<u>Suffix.</u> The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2rd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	В.
February 28	S	August 31	C, E
March 31	L, P	September 30	F. G
April 30	Q, R, 9	October 31	H. N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	IKO

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

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DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA Certificate of Registration (Exhibit J). DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration (Exhibits K, L). A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The Quarterly DEA Exception Report (Exhibit N) is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office will check this type of situation. Calls to the local DEA office should be documented on a Regulatory Agency Contact Form (Form #1).

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.

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Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. (21 CFR 1301.51)

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a Limited Power Of Attorney (Form #25) that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the Power Of Attorney and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. Refer to DEA Correspondence 8/25/93.

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

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Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

<u>Prefix.</u> The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

<u>Suffix.</u> The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

- W- Manufacturer
- Y Distributor
- V Retail Distributor
- X Importer
- Z Exporter

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ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O).** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant currently is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the DEA Narcotic Blank Log (Form #4), and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

• The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

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- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid. If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.
- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.
- The correct name and address of the supplier from whom the controlled substances
 are being ordered is entered on the form. Only one supplier may be listed on any
 one form.
- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to 21CFR 1305.05(c). The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

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- Order Form Books are received at the division.
- The division logs the order form numbers onto the DEA Narcotic Blank Log.
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the DEA Narcotic Blank Log.
- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations (21 CFR 1305.06).
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor;
 Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

Note: All three copies of voided order forms must be sent to the division.

- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto DEA Narcotic Blank Log. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney (21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a Power of Attorney (Form #2) for each such individual. The Power Of Attorney is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a Notice Of Revocation (Form #3), signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

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Sales of Schedule I and II Substances

Procedure for Filling Order Forms (21 CFR 1305.09)

 The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. Refer to DEA Correspondence 07-18-96.

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green) the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.
- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.
- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.
- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

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Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. Refer to DEA Correspondence 6/29/92.

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a DEA 222 Transmission Log (Form #5) are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure shall not be used unless the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA will not permit, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. Refer to DEA Correspondence 07-18-96 and 08-28-96.

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

- Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.
- 2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.
- 3. Cardinal crossdock employee removes 222s from envelopes and completes DEA222 Transmission Log (Form #5).

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- Cardinal employee faxes 222s to distribution center. This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.
- 5. Fax is received in distribution center by Operations Manager or designee.
- Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.
 - a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.
- 7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.
- 8. Operations Manager or designee delivers faxed 222s to the vault.
- 9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

- 1. Customer faxes 222 directly to the distribution center.
- 2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.
- a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.
- 3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.
- 4. Operations Manager or designee delivers faxed 222 to the vault.
- 5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

 The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.

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- The supplier retains copy 1 (brown) of each order form that has been filled.
- Order forms must be maintained separately from all other records of inspection for two
 years (as are all records of controlled substance transactions). If a purchaser has
 several registered locations, copy 3 (blue) of the executed order forms and any attached
 statements or other related documents (not including unexecuted order forms which
 may be kept elsewhere pursuant to (21 CFR 1305.06 (d)) must be kept at the registered
 location printed on the order form.

Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms (21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:
 - (1) Is not complete, legible, or properly prepared, executed, or endorsed; or
 - (2) Shows any alteration, erasure, or change of any description.
- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.
- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with 21 CFR 1305.13. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.
- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's
 registration number, items specified or quantities, or there is improper execution or
 endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.

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- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.
- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc.
 if the customer's order is correct in all respects except that it is specified in error; for
 example, specifies capsules and the product requested is properly designated and
 supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

• If the number of packages, size of package, or strength has been altered by the person preparing the order form.

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- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code number is listed).
- Size of package incorrectly stated (quantity may be reduced).
- · Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but
 a single item has a non-correctable defect, this item may be canceled in lieu of
 returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

Cancellation and Voiding of Order Forms (21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.
- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an Order Form Rejection Notification (Form #6). The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.
- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser of the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a Narcotic Order Review Form (Form #7) for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

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Procedure for Endorsing Order Forms (21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown) and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with 21 CFR 1305.09(b),(c) and (d) including shipping all substances directly to the purchaser.
- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (blue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

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Return of Unused Order Forms (21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to 21 CFR 1301.45 or 1301.46 of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

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REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory

To be taken on December 31

Initial Inventory

To be taken on the effective date that a

substance becomes reportable

Transaction Reporting

Quarterly, or, with DEA permission,

monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

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Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual ARCOS OCR Form - DEA Form 333 - (Form #9).

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10). Reports must be submitted within seven (7) days of the incident. Reporting intransit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on DEA Form 106 should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

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Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11) in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on ARCOS OCR Form 333.

Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files DEA Form 41. Refer to DEA Correspondence 8/12/94 for additional information.

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidently breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. Refer to DEA correspondence 11/17/97.

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish written criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish reasonable criteria based upon customer purchasing patterns and then to adhere to them in monitoring orders.

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Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

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STRUCTURAL SECURITY

Schedule II Controlled Substances

(21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations (21 CFR 1301.72(b)) provide that Schedule III through V controlled substances must be secured as follows:

• In a cage located within the building on the premises meeting the specifications in 1301.72(b)(4)(ii-iv) and Section 1301.72 (b)(3)(ii)(a)(b), which read as follows:

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21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
 - (a) At least one inch in diameter;
 - (b) Set in concrete or installed with lag bolts that are pinned or brazed; and
 - (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be
 erected which reaches and is securely attached to the structural ceiling of the building. A
 lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at
 least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b) (3)(ii)."

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:
- (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
- (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination
- The controlled substance section also provides:

 The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

Alternate: Where swinging cage doors are installed, hinges are properly secured.

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Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b) provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization should be posted, in plain sight, in the secured area. An additional copy of the authorization letter should be retained by division management.

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

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ACCESS CONTROL

General Warehouse

It is the policy of Cardinal to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs should be posted on all warehouse entrances regarding limited access (Exhibit B).

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Division Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

"The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." (21 CFR 1301.72(d))

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Division management maintains an Access and Surveillance List (Form #16) of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list should be posted along with a "Restricted Area" (Exhibit C) sign on the door(s) of the vault and cage.

Temporary employees should never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system should include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees should keep passwords to themselves and periodically change them to prevent access by others. Access should be limited for inventory adjustments, customer licensing information and financial records.

Computer room access should be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

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PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter should be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures should be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. Refer to Drug Thefts/Losses within Required Reports to DEA. The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to 21 CFR 1301.74 (e) upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them (21 CFR 1301.74c).

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

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FOIA Confidential Treatment Requested By Cardinal

Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number
- National Drug Code

Quality Control

All controlled substance orders should be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package should be labeled with the name of the customer. There should be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

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FOIA Confidential Treatment Requested By Cardinal

Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form - DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor should be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo should remove the product from inventory. Proof of delivery should be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item. The Selected Item Audit Report (Exhibit I) gives all movement purchases, returns, sales and inventory adjustments for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances should only be made after a thorough research. Documentation should be kept on file to support any adjustments.

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FOIA Confidential Treatment Requested By Cardinal

Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center should be opened by at least two employees. These employees should meet at a safe, well-lighted, off-site location. The employees should then proceed to the distribution center and one employee should enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure should be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

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SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with 21 CFR 1301.90 and Cardinal's policy which requires all prospective employees to consent to a drug test and a criminal record check. Delivery Vehicle Security Rules (Form #17) are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

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Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do no indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules (Form #17) are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer

level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

<u>Durability</u> A seal must be strong enough to prevent accidental breakage during normal use.

<u>Design</u> The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

<u>Tamperproof</u> The seal should provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

<u>Individually Identifiable</u> Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

<u>Time of Application</u> Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

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<u>Verification</u> Seal examination and verification at every stop such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log. Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a Will Call Log (Form #18) that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

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PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a Pre-Employment Waiver (Form #19) consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment should not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a Post-Employment Security Data Information Sheet (Form #20). The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the Test for Distribution Center Employees Handling Controlled Substances (Appendix B) as well as the Post-Employment Security Data Information Sheet. The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check should be performed prior to the distribution center manager assigning the employee to the controlled substance area.

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Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription
 or reporting to work or working under the influence of alcohol or a controlled substance
 without a medical prescription is strictly prohibited. If an employee requires
 medication which may affect their performance, they should notify their supervisor
 immediately. DEA regulations regarding this should be posted in the facility (Exhibit
 D).
- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.
- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.
- Protection of Company property is a responsibility all employees must share. Any
 employee discovering theft, loss, or malicious damage has an obligation to report the
 incident immediately to his supervisor.
- Fighting or instigating a fight with an employee, customer, or supplier while on Company property is strictly prohibited. No permanent personnel action will be taken until there is a complete investigation by Management.
- Tampering with or breaching Company security systems or policies is prohibited.
- Theft or unauthorized removal or use of Company or another employee's property is prohibited.
- Possession of firearms or illegal weapons on Company property is prohibited.
- Employees must use their own card entry access card, and access cards should not be loaned to other employees. Lost access cards should be reported to Management immediately.
- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.
- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.
- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the
 facility. Signs to this affect should be posted throughout the distribution center
 (Exhibit E). Random periodic inspections could serve as a deterrent to internal theft.

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- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.
- Visitor's entering the distribution center should be asked to sign in on a Visitor's Log (Form #21), indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor should wear a badge and must be escorted during their stay.
- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.
- Coats and pocketbooks are not allowed in the warehouse.
- Employees are to adhere to the posted access list for the cage and vault area.
- A Miscellaneous Security Log (Form #22) should be used to document any minor security-related incidents that occur but do not need to be explained in detail.

Security rules should be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled Violence Prevention Procedures (Exhibit G) should be posted in conspicuous locations throughout the distribution center. These procedures should be reviewed with distribution center employees on a routine, periodic basis. It is paramount that all employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.
- Make it a habit to check your rear view mirror to see if you are being followed. If
 you suspect that you are being followed, obtain a description of the vehicle, the
 license number and the occupants. Proceed to the local police station; if this is not
 possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.

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- In the event of a robbery:
 - a. Offer no resistance.
 - b. Stay calm.
 - c. Be observant.

Driver security rules should be distributed to all drivers and a signature obtained to document receipt.

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Test for Employees Handling Controlled Substances

Name	
Location	
Date	

January 12, 2000

Company Policy

Per the <u>DEA Compliance Manual</u>, anyone allowed unsupervised access to the cage or vault in order to pick controlled substances orders must complete the <u>Test for Employees Handling Controlled Substances</u> as well as the Post-Employment Security Data Information Sheet. The test and this form must then be submitted to the Corporate Compliance Department in Dublin, Ohio. Corporate Compliance will grade the test. Each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area, an in-depth background check will be performed. The results of this background check along with the individual's test score will be shared with the Distribution Center Manager. The background check must be performed prior the Distribution Center Manager assigning the employee to the controlled substance area.

Instructions

- 1. Complete the information requested on the cover page.
- 2. Answer all 33 questions completely.
- 3. Complete the form entitled "Post-Employment Security Data Information Sheet", which is included at the end of this test booklet. This form is utilized for the background investigation portion of this testing process. If this form is not completed in full, your authorization to work with controlled substances will be delayed.
- 4. Seal the booklet with the circle provided.
- 5. Return the test booklet to your supervisor or manager to be forwarded to the Corporate Compliance Department to be scored.
- 6. The Corporate Compliance Department will notify the Distribution Center Manager, in writing, of the test score results and completion of the background investigation. This notification memo should be maintained at the distribution center for audit purposes.
- 7. If you have any questions involving this test or the Company's written policy and procedure in regards to the handling of controlled substances, notify the Compliance Department at (614) 757-7109.

1)	There must be an authorized access list for both the cage and the vault?		
	True	False	
2)	DEA form 41 is used in the reporting o	f	
3)	The DEA schedules Drug Wholesalers	for inspection every:	
	a) Yearb) 2 yearsc) 3 years		
	d) They have no set schedule		
4)	Which color copy of the 222 Order Form	ns must be sent to the DEA each	h month?
	a) blueb) green		
	c) brown		
	d) none of the above		
5)	You are allowed to ship controls and nar notifies you by phone of his new addres	cotics to a customer who has m s.	oved as long as he
	True	False	_
6)	The DEA Form 106 is used for reporting substances.	g	of controlled
7)	The cage and vault must be inventoried	at a minimum of:	
	 a) daily for items with movement b) weekly for items with movement c) monthly for all items d) a and c e) b and c 		
8)	You may fill a narcotic blank that has no	o signature?	
	True	False	

9)	The proper schedules listed on the vast (fill in the blanks):	majority of Narcotic Order Forms consist of Schedule
10)	An employee who has knowledge of druhas an obligation to report such information	ag diversion from his employer by a fellow employee ation to a responsible official of the company?
	True	False
11)	A Narcotic Blank (DEA form 222) is go issued.	ood for days from the date it was
12)	DEA fines are calculated at \$	per violation.
13)	It is not necessary to have someone doub the distribution center.	ole check your Narcotic Orders prior to them leaving
	True	False
14)	is the name of computer tape at the end of each month.	f the unit within the DEA that requires us to send a
15)	As a wholesale drug distributor governed Health is required to report suspicious or	d by the Drug Enforcement Administration, Cardinal excessive purchases of controlled substances.
	True	False
16)	Possession, use, sale or purchase of any i and is grounds for immediate termination	illegal drug on the job is contrary to company policy n.
	True	False
17)	In order to accept a Schedule II return from a narcotic blank to the customer.	om a customer, the distribution center must first issue
	True	Falce

18	What is a Contact sheet and when should it be used?
19	The day-gate doors to both the cage and the vault must be selfand selfaccording to Federal Regulations.
20 as	Controlled Substances may be left outside the approved controlled substances area overnight long as they are left in a locked roll-around cage.
	TrueFalse
21 DE) You may store other items inside the vault as long as you have written permission from the EA.
	True False
the	The rule book used by the DEA to enforce regulations on the drug wholesale industry goes by initials "C.F.R.". These initials stand for: The "Selected Item Audit Report" lists:
b) c)	All receipts of a controlled substance All sales of a controlled substance All controlled substance adjustments All transactions of a controlled substance
	It is Cardinal Health, Inc.'s policy to thoroughly discourage returns of scheduled narcotics.
	True False
25) An)How often should the report entitled "Ingredient Limits Report" or "Suspicious Order allysis" be generated at your Distribution Center?
b) c)	Daily Once a week Once a month Quarterly

Tmie	77.1
True	False
) The responsibility of ver	ifying a customer license rests with:
The DEA	
) The Distribution Center	
) Corporate Headquarters	
) Regional Headquarters	
8)You may sign a 222 narce	otic order form if the customer gives you permission over the phone.
	False
nswers to frequently asked o	a manual entitled <u>DEA Compliance Manual</u> which contains questions about controlled substance procedures.
True	False
1) A customer calls your displanks but to send the control federal Regulations?	stribution center and asks you to fill an order involving one of his lled substances to another location. Is this a violation of the Code of
Yes	No
2) It is advisable that you us Order Form) in case you mak	se white-out or a pencil when working with DEA Form 222 (Narcotic te a mistake.
True	False
 All visitors at your Distrimployee on the authorized a 	bution Center entering the cage or vault area must be escorted by an access list?
True	False

Thank you for completing this test on the handling of controlled substances. Please return this test to your supervisor. He/She will send the test the Cardinal Health, Inc. Corporate Compliance Department in Dublin, Ohio for grading. Your Distribution Center Manager will be notified of your score as soon as your test is graded.





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DEA COMPLIANCE MANUAL

APPENDIX C

DEA Field Offices





Atlanta Division

Richard B. Russell Federal Building 75 Spring Street, S.W., Suite 740 Atlanta, GA 30303 (404) 331-4401 Fax: (404) 331-7340 Area Covered: Georgia, North Carolina, South Carolina, Tennessee

Charleston Resident Office

5900 Core Avenue Suite 100 North Charleston, SC 29406 (803) 308-6660 Fax: (803) 308-6670

Charlotte Resident Office

Nine Woodlawn Green Suite 200 Charlotte, NC 28217 (704) 344-6188 Fax: (704) 344-6795

Columbia Resident Office

Strom Thurmond Federal Building 1835 Assembly Street, Room 1472 Columbia, SC 29201 (803) 765-5251 Fax: (803) 765-5410

Columbus Resident Office

120 12th Street Room 316 Columbus, GA 31902 P.O. Box 1565 Columbus, GA 31902 (706) 649-7850 Fax: (706) 649-7872

Greensboro Resident Office

1801 Stanley Road Suite 201 Greensboro, NC 27407 (910) 547-4210 Fax: (910) 547-4215

Knoxville Resident Office

1721 Midpark Drive 3rd Floor Knoxville, TN 37921 (423) 584-9364 Fax: (423) 584-8763

Memphis Resident Office

Morgan Keegan Tower, Suite 500 50 N. Front Street Memphis, TN 38103 (423) 544-3396 Fax: (423) 544-3025

Nashville Resident Office

Estes Kefauver Building 801 Broadway, Room 500 Nashville, TN 37203 (615) 736-5988 Fax: (615) 736-2221

Savannah Resident Office

Smith Kelly Building 300 Drayton Street, Suite 401 Savannah, GA 31401 (912) 652-4286 Fax: (912) 652-4050

Wilmington Resident Office

Two Princess Street, Room 322 Wilmington, NC 28401 (910) 343-4513 Fax: (910) 343-4463

Chicago Division

John C. Kluczynski Federal
Building
230 S. Dearborn Street, Room 1200
Chicago, IL 60604
(312) 353-7875
Fax: (312) 886-8439
Area Covered: Illinois, Indiana,
Minnesota, North Dakota,
Wisconsin

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Fargo Resident Office

One N. Second Street Suite 302 Fargo, ND 58102 (701) 239-5331 Fax: (701) 239-5248

Green Bay Post of Duty (Brown County/MJG Unit)

PO Box 12734 Green Bay, WI 54307-2734 (414) 448-6241 Fax: (414) 448-6376

Indianapolis Resident Office

Minton-Capehart Federal Building 575 N. Pennsylvania St., Room 290 Indianapolis, IN 46204 (317) 226-7977 Fax: (317) 226-7703

Madison Post of Duty

PO Box 92812 Madison, WI 53701-0981 (608) 264-5111 Fax: (608) 264-5116

Merrillville Resident Office

1571 E. 85th Avenue , Suite 200 Merrillville, IN 46410 (219) 681-7000

Milwaukee Resident Office

1000 N. Water Street, Suite 1010 Milwaukee, WI 53202 (414) 297-3395 Fax: (414) 297-1169

Minneapolis Resident Office

Federal Building 110 S. Fourth Street, Room 402 Minneapolis, MN 55401 (612) 348-1700 Fax: (612) 348-1708





Rockford Resident Office

420 W. State Street Rockford, IL 61101 (815) 987-8034

Springfield Resident Office

Illinois Business Center 400 W. Monroe Street, Suite 302 Springfield, IL 62704 (217) 492-4504 Fax: (217) 492-4507

Dallas Division

1880 Regal Row
Dallas, TX 75235
(214) 640-0801
Fax: (214) 649-0895
Area Covered: Oklahoma, Texas
(Northern)

Fort Worth Resident Office

Fritz W. Lanham Federal Building 819 Taylor Street, Room 13A33 Fort Worth, TX 76102 (817) 978-3455 (817) 978-4128

Lubbock Resident Office

5214 68th Street, Suite 401 Lubbock, TX 79424 (806) 798-7189 Fax: (806) 794-3149

Midland Resident Office

1004 N. Big String, Room 225 Midland, TX 79701 (915) 686-0356 Fax: (915)682-3016

Oklahoma City District Office

3909 N. Classen Blvd., Suite 100 Oklahoma City, OK 73118 (405) 424-2213 Fax: (405) 524-3448

Tulsa Resident Office

5100 E. Skelly Drive, Suite 570 Tulsa, OK 74135-6548 (918) 581-6391 Fax: (918) 581-6439

Tyler Resident Office

909 ESE Loop 323, Suite 280 Tyler, TX 75701 (903) 534-0472

Detroit Division

Rick Finley Federal Building
431 Howard
Detroit, MI 48226
(313) 234-4000
Fax: (313) 234-4141
Area Covered: Kentucky, Michigan,
Ohio

Cincinnati Resident Office

Federal Office Building 550 Main Street, Room 8504 Cincinnati, OH 45202 (513) 684-3671 Fax: (513) 684-3672

Cleveland Resident Office

Courthouse Square Development 310 Lakeside Avenue, #395 Cleveland, OH 44113 (216) 522-3705 Fax: (216) 522-3704

Columbus Resident Office

78 E. Chestnut Street Columbus, OH 43215 (614) 469-2595 Fax: (614) 469-5788

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Grand Rapids Resident Office

65 Monroe Center, N.W. Grand Rapids, MI 49503 (616) 456-2541 Fax: (616) 456-2001

Lexington Resident Office

1500 Leestown Road, Room 308 Lexington, KY 40511 (606) 233-2479 Fax: (606) 233-2590

Louisville Resident Office

New Federal Building, Room 1006 600 Dr. Martin Luther King Place Louisville, KY 40202 (502) 582-5908 Fax: (502) 582-5535

Saginaw Resident Office

301 E. Genessee, Fourth Floor Saginaw, MI 48607 (517) 758-4133 Fax: (517) 758-4013

Toledo Resident Office

234 N. Summitt Street, Room 106 Toldeo, OH 43603 (419) 259-6490 Fax: (419) 259-3725

Houston Division

333 W. Loop N.
Suite 300
Houston, TX 77024
(713) 681-1771
Fax: (713) 220-2378
Area Cavered: Texas (Southern)

Alpine Resident Office

810 N. 2nd Street Alpine, TX 79830 P.O. Box 1282 Alpine, TX 79820 (915) 837-3421 Fax: (915) 837-2701





Austin Resident Office

9009 Mountain Ridge Drive Austin, TX 78759 (512) 346-2486 Fax: (512) 346-0825

Beaumont Resident Office

350 Magnolia, Suite 290 Beaumont, TX 77701-1899 (409) 839-2461 Fax: (409) 839-2551

Brownsville Resident Office

1100 FM 802, Suite 200 Brownsville, TX 78521 (210) 504-4100 Fax: (210) 504-4118

Corpus Christi Resident Office

Wilson Plaza, Suite 300 606 N. Carancahua Corpus Christi, TX 78476 P.O. Box 2443 Corpus Christi, TX 78403 (512) 888-0150 Fax: (512) 888-0199

Eagle Pass Resident Office

342 Rio Grande Room 102 Eagle Pass, TX 78852 (210) 773-5378 Fax: (210) 773-3008

El Paso District Office

700 E. San Antonio Street Suite D-701 El Paso, TX 79901 (915) 534-6400 Fax: (915) 534-6034

Galveston Resident Office

6000 Broadway, Suite 104 Galveston, TX 77551 (409) 766-3568 Fax: (409) 766-3570

Laredo Resident Office

4804 N. Bartlett, Building 1050 Laredo, TX 78041 P.O. Drawer 2307 Laredo, TX 78044-2307 (210) 722-5201 Fax: (210) 726-2221

McAllen District Office

1919 Austin Street McAllen, TX 78501-7030 (210) 618-8400 Fax: (210) 618-8478

San Antonio District Office

10127 Morocco, Suite 200 San Antonio, TX 78216 (210) 525-2900 Fax: (210) 525-2930

Los Angeles Division

Roybal Federal Building 255 E. Temple Street, 20th Floor Los Angeles, CA 90012 (213) 894-2650 Fax: (213) 894-4244 Area Covered: California (Southern), Hawaii, Nevada

Hawaii District Office

Honolulu, HI 96813 P.O. Box 50163 Honolulu, HI 96850 (808) 541-1930 Fax: (808) 541-3048

Nevada District Office

Foley Federal Building & U.S. Courthouse 300 Las Vegas Blvd. S., Suite 204 Las Vegas, NV 89101-0023 (702) 388-6635 Fax: (702) 388-6894

Orange County Resident Office

Federal Building 34 Civic Center Plaza Santa Ana, CA 92712 PO Box 12609 Santa Ana, CA 92712 (714) 836-2892 Fax: (714) 836-2925

Reno Resident Office

300 E. Second Street, Suite 1320 Reno, NV 89501 (702) 784-5617 Fax: (702) 784-5679

Riverside District Office

6377A Riverside Avenue, Suite 220 Riverside, CA 92516-3162 (909) 276-6642 Fax: (909) 276-6269

Ventura Resident Office Office

770 Padeo Camarillo, 3rd Floor Camarillo, CA 93010 (805) 383-6454 Fax: (805) 383-6464

Miami Division

8400 N.W. 53rd Street Miami, FL 33166 (305) 590-4870 Fax: (305) 590-4500 Area Covered: Nassau, Bahamas, Florida

Fort Lauderdale District Office

1475 W. Cypress Creek Rd., Ste. 301 Fort Lauderdale, FL 33309 (305) 356-7700

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Fort Meyers Resident Office

12730 New Brittany Blvd., Suite 501 Fort Myers, FL 33907 (941) 275-3662 Fax: (941) 275-8945

Gainesville Resident Office

235 S. Main Street, Suite 202 Gainesville, FL 32601 (352) 371-2077 Fax: (904) 375-4356

Jacksonville Resident Office

4077 Woodcock Drive, Suite 210 Jacksonville, FL 32207 (904) 232-3566 Fax: (904) 232-2501

Key Largo Resident Office

95360 Overseas Highway, Suite 6 Key Largo, FL 33037 P.O. Box 2930 Key Largo, FL 33037 (305) 852-7874 Fax: (305) 536-5485

Orlando Resident Office

Heathrow Business Center 300 International Pkwy., Suite 424 Heathrow, FL 32746 (407) 333-7000 Fax: (407) 333-7012

Panama City Resident Office

5323 W. Highway 98, Suite 215 Panama City, FL 32401 (904) 769-3407 Fax: (904) 769-4118

Tallahassee Resident Office

3384 Capitol Circle N.E. Tallahassee, FL 32308 (904) 942-8417 Fax: (904) 942-8420

Tampa District Office

5426 Bay Center Drive Tampa, FL 33609 (813) 228-1268 Fax: (813) 228-1281

West Palm Beach Resident Office

1818 S. Australian Ave., Suite 300 West Palm Beach, FL 33409 (561) 684-8000

Midwest Division

United Missouri Bank Building 7911 Forsyth Blvd., Room 500 St. Louis, MO 63105 (314) 425-3241 Fax: (314) 425-3245 Area Covered: Illinois (Southern), Iowa, Kansas, Missouri, Nebraska, South Dakota

Cape Girardeau Resident Office

339 Broadway, Room 158 Cape Girardeau, MO 63701 (573) 334-1534 Fax: (573) 335-4117

Des Moines Resident Office

Federal Building 210 Walnut Street, Room 937 Des Moines, IA 50309 (515) 284-4700 Fax: (515) 284-4920

Kansas City Resident Office

8600 Farley Street, Suite 200 Overland Park, KS 66212 (913) 236-3257 Fax: (913) 236-3186

Omaha Resident Office

Old Federal Building 106 S. 15th Street, Room 1003 Omaha, NE 68102 (402) 221-4222 Fax: (402) 221-4225

Sioux Falls Resident Office

Shriver's Building 230 S. Phillips Avenue, Suite 407 Sioux Falls, SD 57102 (605) 330-4421 Fax: (605) 330-4420

Springfield Resident Office

901 St. Louis Street, Suite 301 Springfield, MO 65806 (417) 831-3948 Fax: (417) 831-0607

Wichita Resident Office

1919 N. Amidon, Suite 330 Wichita, KS 67203 (316) 838-2500 Fax: (316) 838-9123

New England Division

50 Staniford Street, Suite 200
Boston, MA 02114
(617) 557-2100
Fax: (617) 557-2135
Area Covered: Connecticut, Maine,
Massachusetts, New Hampshire,
Rhode Island, Vermont

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DEA Regional Offices



Bridgeport Resident Office

915 Lafayette Blvd., Room 200 Bridgeport, CT 06604 (203) 579-5591 Fax: (203) 579-5530

Burlington Resident Office

P.O. Box 446 Williston, VT 05495 (802) 951-6777 Fax: (802) 951-6489

Cape Cod Resident Office

P.O. Box 708 Barnstable, MA 02630 (508) 362-2117 Fax: (508) 362-8303

Concord Resident Office

197 Loudon Road, Suite 300 Concord, NH 03301 (603) 225-1574 Fax: (603) 225-1543

Hartford Resident Office

Ribicoff Federal Office Building 450 Main Street, Room 628 Hartford, CT 06103 (203) 240-3233 Fax: (203) 240-3703

Logan Airport Task Force

One Harbor Side Drive, Suite 1095 Boston, MA 02128 (617) 561-5764 Fax: (617) 561-5772

Portland Resident Office

1355 Congress Street, Suite D Portland, ME 04102 (207) 780-3331 Fax: (207) 780-3413

Providence Resident Office

Two International Way Warwick, RI 02886 (401) 732-2550 Fax: (401) 739-2576

Springfield Resident Office

1441 Main Street, Suite 1000 Springfield, MA 01103 (413) 785-0284 Fax: (413) 785-0483

New Jersey Division

Peter Rodino Federal Building 970 Broad Street, Room 806 Newark, NJ 07102 (201) 645-6060 Fax: (201) 645-6297 Area Covered: New Jersey

Atlantic City Resident Office

Executive Plaza 2111 New Road, Suite 203 North Field, NJ 08225 (609) 383-3322 Fax: (609) 383-0884

Camden Resident Office

1000 Crawford Place, Suite 200 Mount Laurel, NJ 08054 (609) 757-5407 Fax: (609) 757-5006

New Orleans Division

Three Lakeway Center
3838 N. Causeway Blvd., Suite 1800
Metairie, LA 70002
(504) 840-1100
Fax: (504) 840-1103
Area Covered: Alabama, Arkansas,
Louisiana, Mississippi

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Baton Rouge Resident Office

2237 S. Acadian Thruway, Suite 306 Baton Rouge, LA 70808 (504) 389-0254 Fax: (504) 389-0772

Birmingham Resident Office

234 Goodwin Crest, Suite 420W Birmingham, AL 35209 (205) 290-7150 Fax: (205) 290-7157

Gulfport Resident Office

One Government Plaza, Suite 230 Gulfport, MS 39502 (601) 863-2992 Fax: (601) 868-3112

Jackson Resident Office

Dr. A. H. McCoy Federal Building 100 W. Capitol Street, Suite 1213 Jackson, MS 39269 (601) 965-4400 Fax: (601) 965-4401

Little Rock Resident Office

10825 Financial Parkway, Suite 317 Little Rock, AR 72211-3557 (501) 324-5981 Fax: (501) 324-6900

Mobile Resident Office

900 Western American Cir., Ste. 501 Mobile, AL 36609 (334) 441-5831 Fax: (334) 441-5289

Montgomery District Office

2720-A Gunter Park Drive, West Montgomery, AL 36109 (334) 260-1150 Fax: (334) 223-4430

DEA Regional Offices



Shreveport Resident Office

401 Edwards, Suite 510 Shreveport, LA 71101 (318) 676-4080 Fax: (318) 676-4085

New York Division

99 10th Avenue New York, NY 10011 (212) 337-3900 Fax: (212) 337-2799 Area Covered: New York

Albany Resident Office

Leo W. O'Brien Federal Building, Room 930 Clinton Avenue & N. Pearl Street Albany, NY 12207 (518) 431-4700 Fax: (518) 472-4525

Buffalo Resident Office

28 Church Street, Suite 300 Buffalo, NY 14202 (716) 551-4421 Fax: (716) 551-5160

Long Island Resident Office

175 Pinelawn Road, Suite 205 Melville, NY 11747 (516) 420-4500 Fax: (516) 420-6944

Rochester Resident Office

P.O. Box 14210 Rochester, NY 14614 (716) 263-3180 Fax: (716) 263-5870

Syracuse Resident Office

4600 W. Genesee Street Syracuse, NY 13219 (315) 468-2772 Fax: (315) 468-2985

Philadelphia Division

William J. Green, Jr. Federal Building 600 Arch Street, Room 10224 Philadelphia, PA 19106 (215) 597-9530 Fax: (215) 597-6063 Area Covered: Delaware, Pennsylvania

Allentown Resident Office

504 W. Hamilton Street, Suite 2500 Allentown, PA 18101 (610) 770-0940 Fax: (610) 435-6854

Harrisburg Resident Office

228 Walnut Street, Room 579 Harrisburg, PA 17101 P.O. Box 887 Harrisburg, PA 17108-0887 (717) 782-2270 Fax: (717) 782-4851

Pittsburgh Resident Office

William S. Moorehead Federal Bldg. 1000 Liberty Ave., Room 1328 Pittsburgh, PA 15222 (412) 644-3390 Fax: (412) 644-4745

Scranton Post of Duty

401 N. Adams Plaza, Suite 305 Scranton, PA 18503 (717) 782-2270 Fax: (717) 341-9094

Wilmington Resident Office

One Rodney Square 920 King Street, Suite 404 Wilmington, DE 19801 (302) 573-6184 Fax: (302) 573-6296

Phoenix Division

3010 N. Second Street, Suite 301 Phoenix, AZ 85012-3055 (602) 664-5600 Fax: (602) 664-5611 Area Covered: Arizona

Nogales Resident Office

1370 W. Fairway Drive Nogales, AZ 85621-3895 (520) 281-1727 Fax: (520) 281-1850

Sierra Vista Resident Office

500 Fry Blvd., Suite L14 Sierra Vista, AZ 85635-1840 PO Box 2169 Sierra Vista, AZ 85636-2169 (520) 458-3691 Fax: (520) 670-5025

Tucson District Office

3285 E. Hemisphere Loop Tucson, AZ 85706-5014 (520) 573-5500 Fax: (520) 573-5632

Yuma Resident Office

3150 Windsor Avenue, Suite 202 Yuma, AZ 85365-4905 (602) 344-9550 Fax: (602) 344-1444

Rocky Mountain Division

115 Inverness Drive, East Englewood, CO 80112 (303) 705-7300 Fax: (303) 705-7414 Area Covered: Colorado, New Mexico, Utah, Wyoming

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DEA Regional Offices



Albuquerque District Office

301 Martin Luther King Blvd., N.E. Albuquerque, NM 87102 (505) 766-8925 Fax: (505) 766-8960

Cheyenne Resident Office

J. C. O'Mahoney Federal Building 2120 Capitol Avenue, Room 7010 Cheyenne, WY 82001 (307) 772-2391 Fax: (307) 772-2399

Colorado Springs Resident Office

111 S. Tejon, Suite 306 Colorado Springs, CO 80903 P.O. Box 350 Colorado Springs, CO 80901 (719) 471-1749 Fax: (719) 471-3647

Glenwood Springs Resident Office

401 23rd Street, Suite 300 Glenwood Springs, CO 81601 (970) 945-0744 Fax: (970) 945-8247

Las Cruces Resident Office

Loretto Town Center 505 N. Main Street, Suite 350 Las Cruces, NM 88001 (505) 527-6950 Fax: (505) 527-6966

Salt Lake City Resident Office

American Plaza III 47 West 200 South, Suite 401 Salt Lake City, UT 84101 (801) 524-4156 Fax: (801) 524-5364

San Diego Division

4560 Viewridge Avenue San Diego, CA 91950 (619) 585-4200 Fax: (619) 585-4224 Area Covered: California (Border

Carlsbad Resident Office

5973 Avenida Encinas, Suite 220 Carlsbad, CA 92008 (619) 931-2666 Fax: (619) 931-5974

Imperial County Resident Office

2425 LaBrucherie Road Imperial, CA 92251 (619) 355-0857 Fax: (619) 355-2946

San Ysidro Resident Office

406 Virginia Avenue San Ysidro, CA 92173 (619) 662-7115

San Francisco Division

450 Golden Gate Avenue San Francisco, CA 94102 P.O. Box 36035 San Francisco, CA 94102 (415) 436-7860 Fax: (415) 436-7810 Area Covered: California (Northern)

Fresno Resident Office

1260 M Street, Room 200 Fresno, CA 93720 (209) 487-5402 Fax: (209) 487-5287

Monterey Resident Office

2560 Garden Road, Suite 207 Monterey, CA 93940 P.O. Box 3182 Monterey, CA 93942-3182 (408) 648-3050 Fax: (408) 648-3056

Sacramento Resident Office

1860 Howe Avenue, Suite 250 Sacramento, CA 95825 (916) 566-7160 Fax: (916) 566-7177

San Jose Resident Office

One N First Street, Suite 405 San Jose, CA 95113 (408) 291-7235 Fax: (408) 291-7720

Seattle Division

 220 W. Mercer, Suite 104
 Seattle, WA 98119
 (206) 553-5443
 Fax: (206) 553-1576
 Area Covered: Alaska, Idaho, Montana, Oregon, Washington

Anchorage Resident Office

555 Cordova Street, Suite 600 Anchorage, AK 99501 (907) 271-5033 Fax: (907) 271-3097

Billings Resident Office

303 N. Broadway, Suite 302 Billings, MT 59101 (406) 657-6020 Fax: (406) 657-6047

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Blaine Resident Office

165 Second Street Blaine, WA 98230 P.O. Box 1680 Blaine, WA 98231 (360) 332-8692 Fax: (360) 332-5704

Boise Resident Office

607 N. Eighth Street, Fourth Floor Boise, ID 83702 (208) 334-1620 Fax: (208) 334-9253

Eugene Resident Office

Federal Building 211 E. Seventh Avenue, Room 230 Eugene, OR 97401 (541) 465-6861 Fax: (541) 465-6796

Medford Resident Office

310 Sixth Street, Room B-3 Medford, OR 97501 (541) 454-4407 Fax: (541) 776-4263

Portland Resident Office

Green Wyatt Federal Building 1220 S.W. Third Avenue, Room 1525 Portland, OR 97204 (503) 326-3371 Fax: (503) 326-2341

Spokane Resident Office

1124 W. Riverside, Suite L300 Spokane, WA 99201 (509) 353-2964 Fax: (509) 353-2963

Yakima Resident Office

402 E. Yakima Avenue Yakima, WA 97501 PO Box 4025 Yakima, WA 97501 (509) 454-4407 Fax: (509) 454-4413

Washington, D.C. Division

400 Sixth Street, S.W., Suite 2558
Washington, DC 20024
(202) 401-7834
Fax: (202) 401-7061
Area Covered: District of Columbia, Maryland, Virginia, West Virginia

Baltimore District Office

200 St. Paul Place, Suite 2222 Baltimore, MD 21202 (410) 962-4800 Fax: (410) 962-3470

Charleston Resident Office

Union Square 2 Monongala, Suite 202 Charleston, WV 25302 (304) 347-5209 Fax: (304) 347-5212

Norfolk Resident Office

Federal Office Building 200 Granby Street, Room 320 Norfolk, VA 23510 (804) 441-3152 Fax: (804) 441-6639

Richmond Resident Office

8600 Staples Mill Road, Suite B Richmond, VA 23228 (804) 771-2871 Fax: (804) 771-8167

Roanoke Resident Office

210 Franklin Road, SW Roanoke, VA 24011 (540) 857-2555

> D-12 April, 1997





4 1991 Wilson Janes Company

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019213

DEA COMPLIANCE MANUAL

APPENDIX D

Forms and Exhibits

FORMS AND EXHIBITS

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FOIA Confidential Treatment Requested By Cardinal

CONFIDENTIAL

REGULATORY AGENCY CONTACT FORM

FORM NUMBER:

DEA#1

FUNCTION:

Used to document regulatory agency visits, inspections, and contacts. Provides Corporate Compliance Department with a means to monitor regulatory agency activity on a national level.

DISTRIBUTION:

This two part form is to be completed as needed for any and all agency contacts. One copy must be sent to the Corporate Compliance Department in Dublin by the 15th of the following month. One copy to file.



REGULATORY AGENCY CONTACT FORM

				/
Division ?	Vame		Date	Time
t was made with:				
D.E.A. Represe	ntative			•
FDA Represent	ative	Oth		
t mais mada har			(Please	indicate agency)
Telephone		Visit at Division		Visit at Agency
t initiated by:		Division		Agency
, ADDRESS, AND	TELEP	HONE NUMBER O	F REPR	ESENTATIVE
		(Title)		
		(Office working out o	af)	
		A-A-3		*->
	•	-		=
	RECOR	DS WERE PROVID	ED, CO	MPLETE THE
=				
	-			
ivery Method:				
ivery Method: t/Delivered By:	ED?	☐ Yes □) No	
ivery Method: t/Delivered By: DW-UP REQUIRI		Yes [_	
ivery Method: t/Delivered By: DW-UP REQUIRI		-	М:	
	t was made with: D.E.A. Representation FDA Representation t was made by: Telephone t initiated by: , ADDRESS, AND OSE OF CONTACT E), REPORTING SUSI	D.E.A. Representative FDA Representative t was made by: Telephone t initiated by: ADDRESS, AND TELEP OSE OF CONTACT (AUDITE), REPORTING SUSPICIOUS CORMATION OR RECORDWING:	t was made with: D.E.A. Representative	t was made with: D.E.A. Representative CREPTED STATE BOARD OF REPRESENTATIVE FDA Representative CPlease t was made by: Telephone Visit at Division Telephone Commation (State) (State

DUB 1301

POWER OF ATTORNEY FOR DEA ORDER FORMS

_ FORM NUMBER:

DEA #2

FUNCTION:

Used to authorize specific employees to obtain and execute

order forms (DEA Form 222).

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019218

POWER OF ATTORNEY FOR DEA ORDER FORMS

	(Division Name)
	(Address)
	·
	(DEA Number)
registra Control appoin of attor to exect in requision of 308 of the Co	the undersigned, who is authorized to sign the current application for ation of the above-named registrant under the Controlled Substances Act or olled Substances Import and Export Act, have made, constituted, and ated, and by these presents, do make, constitute and appoint (name rney-in-fact), my true and lawful attorney for me in my name, place and stead, cute applications for books of official order forms and to sign such order forms anisition for Schedule I and II controlled substances, in accordance with section the Controlled Substances Act (21 U.S.C. 828) and Part 1305 of Title 21 of ode of Federal Regulations. I hereby ratify and confirm all that said attorney awfully do or cause to be done by virtue hereof.
(Signa	iture of person granting power)
I,	(name of attorney-in-fact), hereby affirm that I am the
person	n named herein as attorney-in-fact and that the signature affixed hereto is my
signat	ure.
(Signa	ature of attorney-in-fact) Witnesses:
	1.
	2.
	Signed and dated on the day of, 19, at

NOTICE OF REVOCATION

_ FORM NUMBER:

DEA#3

FUNCTION:

Used to revoke power of attorney.

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019220

NOTICE OF REVOCATION

authorized to sign registrant under the and Export Act. W	the current application for registratice Controlled Substances Act of the Vritten notice of this revocation has this same day.	ion of the above-named Controlled Substances Import
(Signature of person	on revoking power)	<u>, ,</u>
1.		<u></u>
2 Signed and	i dated on the day of	, 19 ,

DEA NARCOTIC BLANK LOG

_ FORM NUMBER:

DEA#4

FUNCTION:

Used to record the order form numbers from the blanks received from DEA. Further information is also logged as

a blank is used.

DEA NARCOTIC BLANK LOG

DATE PRODUCT RECEIVED								
VENDOR / CUSTOMER NAME								
DATE BLANK USED		•						
PO/MRA NUMBER	·		٠.	·				
SENT TO PURCHASING								
HELD BY DIVISION								
BLANK NUMBER								
DATE BLANKS REC'D BY DIVISION								

DEA 222 TRANSMISSION LOG

FORM NUMBER:

DEA # 5

FUNCTION:

Used in conjunction with Faxing Narcotic Order Forms to verify faxed order form quantity and information.

CARDINAL HEALTH DEA 222 TRANSMISSION LOG

CUSTOMER NAME	NUMBER OF LINES	BLANK NUMBER	RECEIVED YE
-			
			+
POTAL AUMODO OF DI ANIZO TO		1	
TOTAL NUMBER OF BLANKS TRA			
INTAL MUNICER OF BENIANS KE	TRANSMITTED BY:		RECEIVED BY

ORDER FORM REJECTION NOTIFICATION

FORM NUMBER:

DEA#6

FUNCTION:

Used to comply with DEA regulation which requires written notification to a customer when all or part of their order

form (DEA Form 222) has been rejected.

<u>-</u>	Date:
-	Name:
T	elephone Number:
Order Forms	forcement Administration has established specific criteria for the acceptance of Federal (DEA Form 222). In some cases, we are required to return the form to you and request ected form before shipping. In other cases, we can make minor changes and process shipment.
Your Federal	Order Form was not complete and/or correct in all respects.
	dled this as follows:
	ssion and/or error indicated below is such that we are not permitted to process this form. Form is altered. Our name and/or address is not acceptable as shown. Sixty days have elapsed from date of execution. Item listed is not a Schedule II product. Item listed has been discontinued. It is still available in, NDC # Package size is incorrect. Product description is incomplete. Number of packages or size is omitted. Lines completed less than actually ordered. Signature omitted. Line number is voided.
	Reference our phone conversation.
	Please submit a new form.
	Please revise attached form and return.
	See example attached.
	es indicated below have been made (as permitted by DEA), and order has been shipped. tice is for informational purposes only. No action on your part is required.
	Our name and/or address has been completed as required.
	Number of line items stated in box provided was more than actually listed. We lined out the blank line(s).
***************************************	You sent all three copies to us. We are returning Copy 3 for your files.
	We corrected the NDC number on line item number
	We modified the dosage form on line item number You requested but the product is only
	supplied as
	Substitution of different size package has been made on line item
	Total product supplied is equal to or less than original request.
	Line item number was not correctable. We cancelled this line and processed rest of order. Please submit new
	form for this item

THANK YOU FOR YOUR COOPERATION.

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019227

NARCOTIC ORDER REVIEW FORM

FORM NUMBER:

DEA#7

FUNCTION:

Used to document order form (DEA Form 222) violations when orders are not filled according to DEA regulations.

CARDINAL HEALTH NARCOTIC ORDER REVIEW FORM

Order Form Not Written in Ink or Not Signed Customer/Registration Number: Unable to I.D. or Altered 60 Day Lapse from Date of Execution	NDC #, Strength or Dosage Form Incorrect " Lines Completed" Box Not Filled In
Unable to I.D. or Altered 60 Day Lapse from Date of	
	"Lines Completed" Box Altered
Item: Unable to I.D. or Altered	Lines Completed Less than Lines Actually Ordered
Size, Number of Packages or Strength Altered, Incorrect or Omitted Strength Dittoed	Our Name and Address or Date Omitted Item Discontinued or Not a Schedule II
	Customer Voided a Line
The resulting action should have been: Void entire order form Void single line Fill in omission	
Fill in omission Appropriate personnel have been reminded of the regulatory requ of order forms that have not been properly prepared.	irements regarding the filling

MCA TRANSACTION REPORT

FORM NUMBER:

DEA#8

FUNCTION:

Used to document any excessive purchase or unusual loss

or activity of ephedrine, pseudoephedrine, and

phenylpropanolamine products.



MCA TRANSACTION REPORT

Excessive Purchase		Loss or Theft		DEA Request	
Supplier:					
Name:					
Business Address:					
City:					
State:					
Zip Code:					
Business Telephone:					
					
Purchaser:					
Name:					
Business Address:					··· - · · · · · · · · · · · · · · · · ·
City:					
State:			•		
Zip Code:					
Business Telephone:					
Identification:					
Shipping Address (If diffe Street: City: State: Zip Code:	rent th	an purchaser addr	ress):		<u>.</u>
Date of Shipment:					
Product Description:					
Quantity and Form of Packaging:					
If Loss or Disappearance:					
Date of Loss:					
Type of Loss:					
Description of Circumstances:		•			
Priori or ori cameration					
	_				

ARCOS TRANSACTION REPORTING

_ FORM NUMBER:

DEA # 9

FUNCTION:

Used to submit correction or additional transactions to

ARCOS

OMB Approval No. 1117 - 0003 ō 一个工程 1 1 may 1 Monters to the Copie of Property and Page TRANSACTION DATE STRENGTH LOT NUMBER <u></u>⊢ !-Ω i∙ DEA ORDER FORM NUMBER Q i. An iterior in the transaction teaceps the transaction code (Field 2) and the delete code (Field 2) are expelled of the height duplication definition coding the entire field to becomplish this. It is necessary that the first flettmost character has held to be duplicated is coded using an equal (-) aga. The equal sign is the only character which can be used for this purpose. NNOP. 1. Characters should be printed neatly and conform as closely as possible to examples below. INSTRUCTIONS FOR CODING FORM ASSOCIATE REGISTRATION **⊻** !· **b** ! H !-ひ!· エ!· ⊃**2**----Retain duplicate for your records. Mail the Origins! of completed form to: LL ! Drug Enforcement Administration ARCOS P.O. Box 28293 Washington, D.C. 20038 - 8293 Ш !∙ MAILING INSTRUCTIONS Al 28 <u>U</u> 1m 1. NATIONAL DRIJE CODE Previous editions may be used <!· 21-∞j. DAUG EJEORCEMENT ADMINISTRATION 1-ARCOS TRANSACTION 91. REPORTING மj. ナル AUTORITHO REGISTRANT MARKET mj-DEA Form - 333 (Fab. 1981) - 333 0 - 5

REPORT OF LOSS OR THEFT OF CONTROLLED

SUBSTANCES (DEA FORM 106)

FORM NUMBER:

DEA #10

FUNCTION:

Used to document and report to DEA any loss or theft of

controlled substances.

DISTRIBUTION:

Original and one copy must be submitted to the local DEA office. One copy to the Corporate Compliance Department in Dublin. Copy(s) to state licensing agency as required. One copy to file. Must be submitted within seven (7) days of

the incident

U.S. DEPARTMENT OF JU REPORT OF THEFT O						OMB APPROVAL No. 1117-0001	•
Federal Regulations require registrants to some Drug Enforcement Administration. omplete the front and back of this form to DEA Office. Retain the triplicate copy fr	ibmit a detelle	d report of	any theft	or loss of Controlled Sub	Bearest	DEA MANUAL AUTHO Diversion Investigators 5 FFS: 630-02	
1. NAME AND ADDRESS OF REGISTRANT	(Include ZIF	Code)		ZIP COI	DE	2. FHONE NO. (Include At	es Code)
J. DEA REGISTRATION NUMBER	4. DATE OF	THEFT O	R LOSS	5. PRINCIPAL BUSINES	S OF REGIS	TRANT (Check ane)	
2 ttr. profix 7 digit suffix				1 Phermecy	=	tributor	
				2 Practitioner 3 Manufacturer 4 Hospital/Clinic	=	thedone Program her (specify)	·:
6. COUNTY IN WHICH 7. WAS T POLICE PO	_	TED TO	B. NAMI	E AND TELEPHONE NU	MBER OF PO	OLICE DEPARTMENT (Includ	e Ares Cod
9. NUMBER OF THEFTS OR LOSSES REGISTRANT HAS EXPERIENCED IN THE PAST 24 MONTHS 7	1 D Nieh	F THEFT t break-in ed robbery	3((Check one and complete Employee pillerage Customer theft	5 Other		
11. IF ARMED ROBBERY, WAS ANYONE: KILLED 7 No Yee (How m	(Yna	-	OF 0	CHASE VALUE TO REC CONTROLLED SUBSTAI (EN 7		13. WERE ANY PHARMACE OR MERCHANDISE TAI No Yes (Est. Vek	LEN 7
INJURED 7 No Yes (How	meny)						
. IF LOST IN TRANSIT, COMPLETE THE Name of Common Cerrier		G: Isme of Co	nsignes		C. Cornig	noo's DEA Registration Numi	•
D. Was the carton received by the customer	E. 1	f received,	did It app	eer to be tempered with ?		you experienced losses in transcrier in the pest ?	eit from th
		□ Y es	_]no	'-	la Yes (How Many) _	
16, WHAT IDENTIFYING MARKS, SYMBO IDENTIFYING THE PRODUCTS ?						ERS THAT WOULD ASSIST	IN
16. IF OFFICIAL CONTROLLED SUBSTA	NCE ORDER	FORMS (E	DEA-222)	WERE STOLEN, GIVE N	IUMBERS	•	·
17. WHAT SECURITY MEASURES HAVE	BEEN TAKE	N TO PRE	VENT FU	TURE THEFTS OR LOS	SES 7		· · · · · · · · · · · · · · · · · · ·
		PRIVA	CY ACT I	NFORMATION		· · ·	
AUTHORITY: Section 301 of the C PURPOSE: Report theft or loss of C ROUTINE USES: The Controlled	Controlled Sub	etances.			equired for st	istirtical and anelytical	
purposes, Disci poses stated:	osures of Inter	mation iro	M. CHE SAR	tem ere made to the follow			
	cal law enforce	ment and	regulatory	agencies for law enforcer	ment and regu	letary purposes.	

LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosege Strength and Form	Quantity	
nples: Oesoxyn	Methamphetamine Hydrochloride	5 Mg Tablets	3 x 100	
Demeral	Meperidine Hydrochloride	50 Mg/ml Vial	5 x 30 mi	
Robitussin A-C	Codeine Phosphate	2 Mg/cc Liquid	12 Pints	
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I certify that the	foregoing information is correct to the best of m	y knowledge and belief.		
gneture	Title		Date	

REGISTRANT'S INVENTORY OF DRUGS

SURRENDERED (DEA Form 41)

FORM NUMBER:

DEA#11

FUNCTION:

Used to document and report to DEA the destruction and

disposal of controlled substances.

DISTRIBUTION:

Two copies must be submitted to the local DEA office. One

copy to the Corporate Compliance Department in Dublin.

One copy to file.

DME	Approval	
No.	1117-0007	

DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION REGISTRANTS INVENTORY OF DRUGS SURRENDERED

PACKAGE No.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and	! ZIP Code in space provided below).	
		Signature of applicant or authorized agent
	٦	
L	ا	Registrant's DEA Number Registrant's Telephone Number
		1

NOTE: REGISTERED MAIL IS REQUIRED FOR SHIPMENTS OF DRUGS
VIA US POSTAL SERVICE (see instructions on reverse of form)

VIA US PUSTAL SEN VICE the instructions on reverse of torm.		CONTENTS (Number of grams, table ts, ounces or ounces or ounces or estiner)	stance Con- tent, (Each	FOR DEA USE ONLY		
NAME OF DRUG OR PREPARATION				DISPOSITION	QUANTITY	
Registrants will fill in Columns 1, 2, 3, and 4 Only.			Unit)		GMS.	MOS.
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				• See Instruction		

Previous edition may be used.

	Number of Con- usiners	CONTENTS (Number of grams, biblets, ounces or other units per contourer)	1 1	FOR DEA USE DNLY		
NAME OF DRUG OR PREPARATION				DISPOSITION	QUANTITY	
					GMS.	MGS
1	2	3	•	5	6	7
7	- 				+	┼
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The controlled substances surrendered in accordance with Title 21 of the controlled substances surrendered in accordance with Title 21 of the controlled packages purporting to contain the drugs listed on this inventory at 2) Destroyed as indicated and the remainder forwarded tape-scaled after veri	nd have bee	n: **(1) Fan	verded ta	pe-scaled without op	ening;	
DATE 18 DESTROY	ED BY:	<u></u>				
•• Strike out lines not applicable. WITNESS	ED 8Y: _	,				

INSTRUCTIONS

- 1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance contact of each unit described in column 3; e.g., morphine sulfate tabe., 3 pkgs., 100 tabe., 1/4 gr. (16 mg.) or morphine sulfate tabe., 1 pkg., 83 tabe., 1/2 gr. (32 mg.), etc.
- 2. All packages included on a single line should be identical in name, content and controlled substance strength.
- 2. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning them drugs should be addressed to the DEA District Office which
- 4. There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.
- 8. Drugs should be shipped tape-scaled via prepaid express or registered mail to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

PRIVACY ACT INFORMATION

AUTHORITY: Section 307 of the Controlled Substances Act of 1970 (P.L. 91-513).

PURPOSE: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposel.

ROUTINE USES: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances.

Disclosures of information from this system are made to the following categories of users for the purposes stated.

- A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

· EFFECT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

KEY LOG

FORM NUMBER:

DEA # 12

FUNCTION:

Used to list personel who have been issued keys.

FOIA Confidential Treatment Requested By Cardinal

CAH SWE 019240

CARDINAL HEALTH	Division		
EY LOG			
	;		
he following person	nel have been issued keys to t	his facility:	······································
			
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gnature			
itle			
Division			
Date			

KEY RECEIPT

_ FORM NUMBER:

DEA # 13

FUNCTION:

Used to document the transfer of a key from the company to

an employee.

Cardinal Health

Key Receipt

Employee Name:	Date:		
Department:	Key Number:		
to prevent any misuse. I will immediately notify the event of theft or any other loss of the key. I w	use of the key and will take all reasonable precautions the Cardinal Health Corporate Security Department in will not have any copies of the key made and will turn in Department when my employment terminates for		
Employee Signature:			

MONTHLY ALARM WALK TEST REPORT

FORM NUMBER:

DEA # 14

FUNCTION:

Used to document proper functioning of alarm system and to maintain records of false alarms. Provides Corporate Compliance Department with information that can be used to evaluate alarm company service and divisional compliance with Company security policies.

DISTRIBUTION:

This two-part form is to be completed at the end of each month. One copy must be sent to the Corporate Compliance Department in Dublin by the 15th of the following month. One copy to file.



MONTHLY ALARM WALK-TEST REPORT

ALARM COMPANY'S NAME NUMBER OF FALSE ALARMS IN THE PAST MONTH LAST FALSE ALARM CORRECTIVE ACTION TAKEN INSTRUCTIONS Please check the following alarm equipment and indicate that it is functioning properly by placing a mark in the space provided. Alarm call-up list is up-to-date Ambush/Duress code on control panel is functioning Sensitivity of all motion detectors is set correctly Boxes and shelves are NOT blocking motion detectors Photoelectric beams have a clean line of sight Door contacts and audible alarms are functioning properly Vault alarm system is functioning properly (scheduled openings & closings) All closed circuit television cameras are working properly All closed circuit television camera monitors are working properly All closed circuit television camera monitors are working properly All robbery buttons are functioning properly (battery back-ups on hand-hele buttons are fresh) All intercoms are working properly Signature of employee completed at the end of each month. Copy must be sent to the	DIVISION FOR THE MONTH OF		
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Signature of employee completing form Date This form is to be completed at the end of each month. Copy must be sent to the	buttons are fresh)		
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This form is to be completed at the end of each month. Copy must be sent to the	Signature of employee completing form	Date	
This form is to be completed at the end of each month. Copy must be sent to the	em to the transfer of the com-	ad of each month. Comy must be sent to the	
Corporate Compliance Office by the 15th of the following month.	inis form is to be completed at the en	15th of the following month	

WHITE - Division

YELLOW - Corporate Compliance

INCIDENT REPORT

FORM NUMBER:

DEA # 15

FUNCTION:

Used to document security-related incidents which occur and require a detailed explanation (i.e., theft, burglary, vandalism).

CARDINAL HEALTH SECURITY DEPARTMENT	Incident Number:
INCIDENT REPORT FORM	
Date of Incident:	. Time:
Nature of Incident:	
Reporting Party:	
Department/Address:	Phone/Ext:
Authorities Natified:	
Evaluis Incident in Detail.	
	
	·
Disposition:	
	•

ACCESS AND SURVEILLANCE LIST

FORM NUMBER:

DEA # 16

FUNCTION:

Used to facilitate compliance with DEA regulation which requires written authorization for cage and vault access.

FOIA Confidential Treatment Requested By Cardinal

CARDINAL HEALTH Division ACCESS AND SURVEILLANCE LIST

The following personnel are permitted unsupervised access to the cage and vault area:		
If any person other than those listed above requires job-related this area, they must be escorted by a person with approved cag		
Signature		
Title		
livision		
Date		

DELIVERY VEHICLE SECURITY RULES

FORM NUMBER:

DEA#17

FUNCTION:

Used to document security measures required by delivery

vehicle drivers.

DELIVERY VEHICLE SECURITY

The following rules are intended to promote safety and security for drivers and their delivery vehicles. They are to be complied with at all times.

- 1. Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- 2. Secure the truck when making a delivery. Roll up all windows, lock all doors, and take the keys with you.
- 3. Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.
- 4. Make it a habit to check your rearview mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop, and call the local police or the office.
- 5. If you break down, stay with your truck. Leave only to call for assistance.
- 6. Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
- 7. In the event of a robbery:
 - A. Offer no resistance.
 - B. Stay calm.
 - C. Be observant.

Driver Signature:	
Witness Signature:	

WILL CALL LOG

_ FORM NUMBER:

DEA # 18

FUNCTION:

· Used to document the pickup of an order by a customer.

FOIA Confidential Treatment Requested By Cardinal

	WILL CALL LOG	
Customer Name		
Customer Number		
Date		
Number of Boxes		
Courier Service Name		
†		
Drivers License Number		
Driver ID# (Cab Number, etc.) _		
l .		
	WILL CALL LOG	
Customer Name		!
Customer Number	Invoice Number	
Date ·		
Number of Boxes	Number of Bags	
Courier Service Name		
1		
Drivers License Number		
•	·	

CONSENT AND RELEASE

FORM NUMBER:

DEA #19

FUNCTION:

Used during employment application process to obtain applicant's consent for background investigation and drug

screening.



CONSENT AND RELEASE:

PLEASE READ THIS NOTICE AND CONSENT FORM CAREFULLY BEFORE SIGNING. YOU WILL BE PROVIDED WITH A COPY OF THIS FORM AT ANY TIME UPON REQUEST.

NOTICE AND CONSENT CONCERNING CONSUMER REPORTS FOR EMPLOYMENT APPLICATIONS AND EMPLOYMENT PURPOSES.

This form, which you should read carefully, has been provided to you because Cardinal Health ("Cardinal Health") will request consumer reports or investigate consumer reports in connection with your application for employment or during the course of your employment with Cardinal Health, if any. These background checks, and/or investigations, will be performed by Cardinal Health, in whole or in part, at Cardinal Health's discretion.

Cardinal Health's applicant background checks and employee investigations will also include the use of consumer reporting agencies to gather and report information to Cardinal Health in the form of consumer or investigative consumer reports, as regulated by federal law. Such reports, if obtained, will be prepared by consumer reporting agencies and may contain information concerning your credit standing or worthiness, character, general reputation, personal characteristics, or mode of living. Cardinal Health is not a consumer-reporting agency.

The type of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to; credit reports, criminal records (for the maximum period permitted by applicable state and federal law), court records, driving records, and/or summaries of educational and employment records and nistories. The information contained in these reports may be obtained by a consumer reporting agency, from public records, or through personal interviews with co-workers, neighbors, friends, associates, current or former employers, or other personal acquaintances. Any information contained in such reports may be taken into consideration in evaluating your suitability for employment, promotion, reassignment or retention as an employee.

If Cardinal Health requests an investigative consumer report to be performed by a consumer reporting agency, as defined by federal law, you will receive a notice indicating that the report has been requested no later than three days after the request is made to the agency. This additional notice, if issued, will provide you with further information pertaining to federal law governing investigative consumer reports. You will not receive a notice if Cardinal Health or a person or entity other than a consumer-reporting agency performs the investigation.

Your consent is required by law before Cardinal Health may obtain a consumer report or investigative consumer report from a consumer reporting agency pertaining to your application for employment and thereafter, during the course of your employment, if any, at Cardinal Health's discretion. Your signature below indicates that you have read and understand that Cardinal Health may request and review a consumer report or investigative consumer report regarding your background, and that you consent to the release of reports to Cardinal Health for employment purposes. This information may also be considered for any future decisions concerning your employment, promotion, reassignment or retention as an employee of Cardinal Health. Your signature additionally reflects your understanding that such consent will remain in effect indefinitely until you revoke it in writing, as described below.

00.8

FOIA Confidential Treatment Requested By Cardinal

Refusal to consent to a consumer report or an investigative consumer report as required by this notice, or any other attempt to interfere or failure to cooperate with Cardinal Health's lawful investigation, may result in rejection of your application, withdrawal of an offer of employment, or corrective discipline; up to and including termination of employment.

CONSENT STATEMENT:

I have carefully read and understand this notice and consent form and, by my signature below, consent to the release of consumer or investigative consumer reports, as defined above, to Cardinal Health in conjunction with my application for employment. I further understand that this consent will apply during the course of my employment with Cardinal Health, should I obtain such employment, and that such consent will remain in effect until revoked in a written document signed by me.

In the event that I wish to refuse or revoke my consent, I understand that I may do so by: 1. Signing the "Refusal or Revocation of Consent Statement" below, or 2. Sending a signed statement, indicating that I revoke my consent for Cardinal Health to obtain a consumer report or investigative consumer report, and submitting to:

Cardinal Health Human Resources 7000 Cardinal Place Dublin, OH 43017

I certify that the information I have provided to Cardinal Health, on this consent and release form, is correct the best of my knowledge and I understand that any falsifications, misrepresentations, and/or omissions result in my disqualification for consideration of employment or, is subsequently employed, my dismissal.		
Name of Applicant/Employee		
Applicant/Employee Signature	Today's Date	
REFUSAL OR REVOCATION OF CONSENT STATEMI (DO NOT SIGN UNLESS YOU HAVE DECIDED THAT YOU W CARDINAL HEALTH OBTAINING A CONSUMER REPORT OR AN I	ILL NOT CONSENT OR WILL NO LONGER CONSENT TO	
I do not consent to Cardinal Health obtaining consumer connection with my application for employment or for a granted my consent, I hereby revoke that consent a immediately after Cardinal Health receives this written rethe revocation to those employees or agents who request	any other employment purposes. If I have previously and understand that such revocation will take effect revocation and has actual knowledge to communicate	
Name of Applicant/Employee	or consumer reports for Cardinal realth.	
Applicant/Employee Signature	Today's Date	

FOIA Confidential Treatment Requested By Cardinal

EMPLOYMENT SECURITY INFORMATION

FORM NUMBER:

DEA # 20

FUNCTION:

Used to conduct background investigations on new

employees.

Cardinal Health			
•	EMPLOYMENT SECURITY INFORMATION	Submitted	
Division:	Supervisor		Ì
Department:	Date of Hire		İ
Name: (First)	(Middle)	(Last)	
Present Address:			
(Street)	(City)	(State) (Zip)	
Time at residence:	County of Residence:	Telephone: ()	
Previous Name	的一种的一种,是一种是一种,是一种,是一种,是一种,是一种,是一种,是一种,是一种,是一		
FILE (FIRSH)		([ast]):([ast]):	
Pravious Rasidance			
(Siree))		(State): (Z[p) (Z[p)	
IIMe at previous residence	County of previous residence	S residence in the second of t	
Social Security Number	Drivers License Number	State	
Date of Birth	Place of Birth Heig	Height Weight Weight	
- 12 Color		Cialdo	

Have you ever been convicted of a crime (felony or misdemeanor), or do you have any pending charges? *

If yes, identify the crime, the date of the conviction, the court where the conviction occurred, and the disposition of the case. Please provide any details you feel are relevant. Conviction of a crime will not automatically disqualify you from employment, but will be considered as a part of the overall evaluation of your qualifications for the position sought

elease Cardinal Health its subsidiaries, affiliates, officers, employees, informants and the Drug Enforcement Administration from liability arising from this Walver: I hereby authorize Cardinal Health, its subsidiaries or affiliates, and the Drug Enforcement Administration to make a complete investigation of me, my former business relations and employment, and any business organization or any other person to give full information and records about me. I hereby nvestigation. Discovery of false information on this sheet may lead to discharge of my employment with Cardinal Health or its subsidiaries or affiliates.

Today's Date Signature

8.00

VISITOR LOG

FORM NUMBER:

DEA #21

FUNCTION:

Used to document any visitor's entering the facility.

FOIA Confidential Treatment Requested By Cardinal

VISITOR LOG

happer 1	NAME	REPRESENTING	TIME IN	TIME OUT	PURPOSE
··· - ··· ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
 					
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				 	-

MISCELLANEOUS SECURITY LOG

FORM NUMBER:

DEA # 22

FUNCTION:

Used to document any minor security-related incidents that occur but do not need to be explained in detail (i.e., false

alarms, open doors, alarm not set, etc.).

FOIA Confidential Treatment Requested By Cardinal

CARDINAL HEALTH MISCELLANEOUS SECURITY LOG

DATE	TIME	NARRATIVE
· · · · · · · · · · · · · · · · · · ·		
Y 		

	·	
		
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	<u> </u>	

DEA INSPECTION REPORT

FORM NUMBER:

DEA #23

FUNCTION:

Used to document an inspection made by the DEA.

FOIA Confidential Treatment Requested By Cardinal

DEA INSPECTION REPORT

This form is to be completed by the Division Manager or his designee and forwarded to the Corporate Compliance Department upon completion of a DEA inspection.

DI	VISION:	DATE:	
A.	General Information		
1.	Initiation Date		
2.	Leader Compliance Investigator		
3.	DEA Office		
4.	Closing Date Exit Interview		
5 .	Total On-Site Days		
6.	Total On-Site Person Hours		
В.	Inventory Accountability Audit		
1.	Number of items audited		
	a) Description and class of items audited:		
<u> </u>			
<u> </u>			_
<u> </u>			_
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-			\dashv
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2.	Audit timeframe in months		
3.	Number of items in variance		

•	Վար	comon room round (Check an that apply)	
	1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12.	Background information Biennial Inventory Recordkeeping DEA Form 222 Physical Security Procedural Security Shipping/Receiving Procedures Registration Verification/Customers ARCOS Suspicious Order Monitoring Destructions Losses/Thefts Pre-Employment Screening Will Calls	
D.	Pleas	se document any significant comments, questions, criting the inspection and exit interview and attach to this r	cisms made by the inspector eport.
E.	Reso Plea	olution (to be completed by Corporate Compliance use attach all related documentation.	Department)
1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11.	DEA Memor Information Court Consecution Total Fines	Follow-Up Letter of Admonition Citation brandum of Understanding nal Hearing al Hearing Proceeding ent Order Violations Acknowledged in M.O.U. Sought Paid ution Date	Yes No Yes No
Sign	ature an	d Title of Person Completing Form	Date
Divis	ion Man	nager's Signature	Date

DEA ON-SITE BACKGROUND INFORMATION

PACKAGE

FORM NUMBER:

DEA # 24

FUNCTION:

Used to provide DEA Investigators with company background information during DEA audits.

FOIA Confidential Treatment Requested By Cardinal

DEA ON-SITE BACKGROUND INFORMATION PACKAGE

	SECTION I	FIRM'S BACKGROUND
A	Company Name:	
-	Address:	
	Telephone Number:	()
	Fax Number:	()
B.	Type of Firm:	
C.	Corporate Headquarters:	
D.	State of Incorporation:	
E.	Subsidiaries:	
F.	Corporate Officers: (See attached	0)
G.	Principle Management Personnel: (List all personnel and include the	
	Name:	
	Title: Length of Service:	
H.	Type of Business:	
	Distribution Area:	
I.	Distribution Area:	
J.	Methods of Distribution (Delivery	Companies):

Hours of Operation:
Number of Employees:
How long at present location:
Controlled substance sales as percentage of total sales:
SECTION II LICENSES AND REGISTRATIONS (attach copies of DEA registration and State licenses).
DEA (See attached):
State (See attached):
SECTION III (Breifly describe when inventories are taken and where records are maintained).
Biennial Inventories:
Periodic Inventories:
SECTIONIV RECORDS / REPORTS (briefly describe the types of records and where maintained)
Purchase Records:
Sales Records:
Return Records:

DEA Form 106: DEA Form 41:	
ARCOS Records:	
Suspicious/Excessive Customer Purchases:	

	SECTION V	PROCEDURES
		emplished with respect to controlled substances).
A.	Receiving:	
В.	Order Filling:	
	U	
C.	Shipping:	•
D.	Returns:	
D.	Retui us.	
	av cart 0.11 TT	
	SECTION VI	SECURITY
A.	Structure of Building:	·
В.	Structure of Vault:	
۷.		
		· · · · · · · · · · · · · · · · · · ·
C.	Structure of Cage:	
D.	Alarm Company:	
	Address:	
E.	Type of Alarm Hardware:	
F.	Type of Circuit (McCulloh Loop, etc	.):
G.	Notification Procedures:	

Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name: Title Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title		
Alarm Company: Law Enforcement: Distribution Center Personnel: Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name: Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: SS# Title Date of Birth: SS#		
Alarm Company: Law Enforcement: Distribution Center Personnel: Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name: Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: SS# Title Date of Birth: SS#		
Alarm Company: Law Enforcement: Distribution Center Personnel: Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name:	Who Responds:	
Law Enforcement: Distribution Center Personnel: Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name: Title Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	Response Time:	
Law Enforcement: Distribution Center Personnel: Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name: Title Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	Alarm Co	отрану:
Persons with Alarm Keys/Passes: (List all personnel and include the following information): Name: Title Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#		orcement:
Clist all personnel and include the following information: Name: Title Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	Distributi	ion Center Personnel:
Clist all personnel and include the following information: Name: Title Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	Persons with Alarm Key	vs/Passes:
Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name:		
Length of Service: Persons with Access to Vault: (List all personnel and include the following information) Name: Title Date of Birth: Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	Name:	Title
(List all personnel and include the following information) Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#		
Name: Title Date of Birth: SS# Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#		
Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	(List all personnel and i	nclude the following information)
Persons with Access to Cage: (List all personnel and include the following information) Name: Title Date of Birth: SS#	Name:	Title
(List all personnel and include the following information) Name: Title Date of Birth: SS#	Date of Birth:	SS#
(List all personnel and include the following information) Name: Title Date of Birth: SS#	Persons with Access to (Care.
Date of Birth: SS#		
Date of Birth: SS#	Name:	Title
Employee Screening procedures (Describe hiring practices):	Date of Birth:	SS#
Employee Screening procedures (Describe hiring practices):		
	Employee Screening pro	ocedures (Describe hiring practices):

Cardinal Health, Inc.: DEA Registered Locations

Distribution Center	Address	DEA Number
Whitmire Dist. Corp. DBA Cardinal Health	7301 Los Voicanes Rd. NW Albuquerque NM 87121	RW0234928
Whitmire Distribution Corp. DBA Cardinal	914 Marcon Blvd. Allantown PA 18103	RW0191938
Whitmire Distribution Corp. DBA Cardinal	801 C St. N.W., Suite B Auburn WA 98001	RW0191813
Whitmire Distribution Corp. DBA Cardinal	2353 Prospect Dr. Aurora IL 60504	RW0231908
Whitmire Distribution Corp. DBA Cardinal	4770 (U) Forest St. Denver CO 80216	RW0192017
Whitmire Distribution Corp. DBA Cardinal	13188 Lakefront Drive Earth City MO 63045	RW0192106
Marmac Distributors, Inc. DBA Cardinal Health	4 Craftsman Road East Windsor CT 06088	RM0125484
Whitmire Distribution Corpora DBA Cardinal	3238 Dwight Road Elk Grove CA 95758	RW0236009
Whitmire Distribution Corp. DBA Cardinal	4 Girbraud Ct. Greensboro NC 27407	RW0243903
Ohio Valley-Clarksburg, Inc. DBA Cardinal Health	6540 Port Road Groveport OH 43125	RR0248179
Whitmire Distribution Corp. DBA Cardinal	7052 Grand Blvd. Ste. 112 Houston TX 77054	RW0191407
Whitmire Distribution Corp. DBA Cardinal	2901 Enloe St. Hudson WI 54106	RW0243725
Whitmire Distribution Corp. DBA Cardinal	7601 NE Gardner Avenue Cansas City MO 64120	RW0191926
Chapman Southeast, Inc. DBA Cardinal Health	2512 West Cott Blvd Knoxville TN 37931	RC0238104

Wednesday, January 05, 2000

Page I of 3

Distribution Center	Address	DEA Number
Cardinal Southeast, Inc DBA Cardinal Health	2045 Interstate Drive Lakeland FL 33805	RC0182080
CORD Logistics	1135 Heil Quaker Blvd. Ste. 100 LaVergne TN 37086	RC0229965
Cardinal Southeast, Inc. DBA Cardinal Health	1240 Gluckstadt Road Madison MS 39110	RC0221236
National Specialty Services, Inc.	556 Metroplex Dr. Nashville TN 37211	RN0184363
Whitmire Distribution Corp. DBA Cardinal	1351 Doubleday Ontario CA 91761	RW0192168
Daly, James W. Inc. DBA Cardinal Health	11 Centennial Drive Peabody MA 01960	RD0108200
Packaging Coordinators, Inc.	3001 Red Lion Road Philadelphia PA 19114	RP0225284
Whitmire Distribution Corp DBA Cardinal	3821 East Broadway Phoenix AZ 85040	RW0224294
Whitmire Distribution Corp. DBA Cardinal	4422 South 38th Place Phoenix AZ 85040	RW0191940
Cardinal Southeast, Inc. DBA Cardinal Health	42 Ross Road Savannah GA 31405	RS0187612
Whitmire Distribution Corp. DBA Cardinal	955 West 3100 South South Salt La UT 84119	RW0191419
Cardinal Syracuse, Inc. DBA Cardinal Health	6012 Molloy Rd. Syracuse NY 13211	PC0003044
Whitmire Distribution Corp. DBA Cardinal	27680 Avenue Mentry Valencia CA 91355	RW0216449
Whitmire Distribution Corp. DBA Cardinal	7500 Mars Drive Waco TX 76712	RB0196522
Ohio Valley-Clarksburg, Inc. DBA Cardinal Health	71 Mil-Acres Dr. Wheeling WV 26003	RO0153609
National PharmPak Services, Inc.	3450 East Pike Zanesville OH 43701	RN0209583

Wednesday, January 05, 2000

Page 2 of 3

Distribution Center	Address		DEA Number		
Williams Drug Dist., Inc.	1000 Linden Ave.		PT0186038	-	
	Zanesville OH	43701	11010000		
National PharmPak Services, Inc	850 Airport Distribution	n Drive	RN0244967		
	Zanesville OH	43701	111027730;		
National PharmPak	1000 Linden Avenue		RN0231427		
Services, Inc	Zanesville OH	43701	***************************************		

Wednesday, January 05, 2000

Page 3 of 3

LIMITED POWER OF ATTORNEY

FORM NUMBER:

DEA#25

FUNCTION:

Used for a change of pharmacy ownership and continuing operation on a previous owner's DEA registration.

LIMITED POWER OF ATTORNEY

 (Name of Registrant) (Address of Registrant)
(DEA Registration Number)

WHEREAS, (hereinafter referred to as "Seller") and (hereinafter referred to as "Buyer"), have executed a Purchase Agreement dated and related documents, all with the intent of transferring a pharmacy known as (the "Pharmacy") and

currently

WHEREAS, the transfer referred to in said Purchase Agreement is to take place, or has taken place, on or about and

WHEREAS, the parties to the Purchase Agreement and this Power of Attorney desire that the business carried on at shall continue without interruption while BUYER obtains a DEA registration and the various licenses necessary in the State of and until the transfers referred to in said Purchase Agreement take place; and

WHEREAS, such licenses are currently possessed by the Seller.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in the Purchase Agreement and related documents, and in an effort to implement the same, I, , who is authorized to sign the current application for registration of the abovenamed registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents do make, constitute, , my true and lawful attorney for me in my name, place, and stead, and appoint to execute applications for books of official order forms and to sign such order forms in accordance with Section 309 of the Controlled Substances Act (21 U.S.C. 828) and Part 305 or Title 21 of the Code of Federal Regulations for Pharmacy located at Such appointment shall authorize buyer to take all actions permitted by the undersigned pursuant to the aforesaid licenses, with respect to the management of the Pharmacy. I hereby ratify and confirm all that said Attorney-in-Fact shall lawfully do or cause to be done by virtue hereof, including the use of the DEA number of Seller until such time as a new DEA number and State pharmacy licenses are issued from the proper federal and state authorities.

IT IS FURTHER UNDERSTOOD that after the Closing Date in the Purchase Agreement, at such time as the undersigned no longer owns the assets of the pharmacy aforementioned, the operation of said pharmacy shall be solely in the control of Buyer and that nothing herein shall be construed so as to cause Buyer to be deemed the employee of the undersigned for any reason whatsoever, and that no action taken by Buyer shall give rise to any liability of the undersigned to any third party.

It is agreed by both parties that this appointment of Attorney-in-Fact shall terminate on the first to occur of Buyer obtaining all necessary licenses to operate the Pharmacy, or , 199 . (Power of Attorney cannot extend beyond 45 days of closing.)

By:

By:

I,

accept the foregoing appointment, and I represent and warrant that I am a registered pharmacist, licensed to practice pharmacy in the State of , and I am the person named herein as Attorney-in-Fact and, that the signature affixed hereto is my signature.

DEA AND ARCOS DIVISION AUDIT RECAP

FORM #:

DEA#26

FUNCTION:

Used to facilitate compliance with DEA record keeping and reporting requirements and assist the Corporate Compliance Department in monitoring divisional compliance and identifying potential problem areas.

DISTRIBUTION:

This form is to be completed at the end of each month. One copy must be sent to the Corporate Compliance Department. One copy to your group office if applicable. One copy must remain on file at the division.

FOIA Confidential Treatment Requested By Cardinal

P-09320_00248



DEA & ARCOS DIVISION AUDIT RECAP

te_	· · · · · · · · · · · · · · · · · · ·		D	ivision		
	DP Number	Product	<u>Counts</u> <u>Actual</u>		<u>QOH</u>	<u>Variance</u>
			<u></u>			
						
				<u> </u>		
						
	Discrepancies to coun	ts and follow-up	action taken:			
	Morgue - no controlle	d substances in n	norgue or in stag	ging area for	customer retu	ırns.
	COMPLIANCE	Yes	No			
	Receiving Area - No	controlled substan	ices left out or i	ınattended in	receiving.	
	COMPLIANCE	Yes	No			
).	Review of prior month			y of narcotic	blanks.*	
	COMPLIANCE					
).	Review of prior mont	h's DEA green co	py of form 222.			
	COMPLIANCE	Yes	No			
	Review of prior mont	h's blue receiving	copy of narcoti	c blanks for p	purchases	
		Yes				
	Division Manager or o	designee has appr	oved and initial	ed blanks for	excessive cus	tomer purchases.
	COMPLIANCE	Yes	_ No			
	DEA form 106 submi	tted timely to DE	A for variances	, losses or the	efts.	
	Date variance oc	curred		. Date loss/	theft ocurred	
	Date form 106 w	as submitted		. Date form	n 106 was sub	mitted
	(attach copy of F					
	DEA Form 41 submit	ted for destruction	n and verification	on of ARCO	S submission.	
	COMPLIANCE	Yes	No			
	Excessive purchase re	port on file with	copies of conta	ct sheets sent	to state and l	ocal DEA offices.
	COMPLIANCE		No			
	ARCOS and DEA Su	bmission control	form with retur	n receipt cop	y, from prior	month.
	COMPLIANCE		No			
(a).	Month-end physical c	ycle counts for v	ault and cage w	ith no variand	ces.	•
	VARIANCES					ariances this month
(b).	Compliance to follow	-up variance pro	cedures.		-	
	-	Yes	No			
	ARCOS errors report					
		Yes	No			
Atta	ch copies of blanks fo	ound not to be in				
	•		-			
			•			
				Div	rision Manage	r's Signature

Run Date: 12/30/94 Run Time: 19:49 Page : 1	e inventory s distribution ss <u>(2-30-94</u> , Regulations:	2/30/94 Date	TABS 0.25MG A 000009-0029-01 UPJOHN COM	#3 TABS 30/300 A 000093-0150-10 LEMMON CO.	TABS 1MG A 000781-1328-05 GENEVA PHA	TABS 65/650 ' A 000008-0085-01 UYETH-AYER	TABS 0.5 MG A 000009-0055-01.UPJOHN COM	TABS A
WHITMIRE DIST CORP- MILWAUKEE CONTROLLED SUBSTANCES INVENTORY	ontains a complete as stocked at this close of business Code of Federal Re INVENTORY, and	INVENTORY Ultrass	XANAX 100 0000	APAP/COD 1000 0000	ALPRAZOLAM 500 0007	WYGESIC 0000	XANAX 100 0000	F.ORINAL
GINVE465 WHIT GINVE46R CONT 3034	The following report Coof Controlled Substance Center Warehouse at the in compliance with the #1304.13 BIENNIAL	Mylam-Alled Dist Center Hanager 2 30 94 also	088-749 242	258~350 118	859-001 19	097-403 39	088-757 228	076-252 12
Progres : Uhse No :			60A#42 0BE	60A+51 256	60A*52 859	60B*21 097	608*22 086	. JB#23 076

- STOP.

ANY UNAUTHORIZED PERSONNE **WAREHOUSE SHOULD BE** NSTRUCTED TO RESPOND REQUESTING ENTRY INT THE FRONT DO

ACTION DISCIPLINARY INAUTHORIZED PERSONNEL SUBJECT

INCLUDING DISCHARGE

THIS ANNOUNCEMENT MADE NECESSARY BY INCREASED HANDLING AND CONTROL OF DANGEROUS DRUGS STATE AND FEDERAL RESTRICTIONS PERTAINING TO THE

EXHIBIT C

RULES AND REGULATIONS AS PUBLISHED BY THE DRUG ENFORCEMENT ADMINISTRATION EFFECTIVE APRIL 17, 1975

1301.91 Employee Responsibility to Report Drug Diversion

Reports of drug diversion by fellow employees is not only a necessary part of an such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the Identity of the employee furnishing A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat security area. The employer shall inform all employees concerning this policy nformation.

1301.92 Illicit Activities by Employees

regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action record of employment, etc., in determining whether to suspend, transfer, terminate or ake other action against the employee.

and Federal restrictions pertaining to the handling and This announcement made necessary by increased control of dangerous drugs

																	EX	HIB	IT F
PAGE 4			MTH INCREASE		800.006		200.00% 250.00%		150.00%		400.00%		300.00x 500.00x 125.00x		600.00% 340.00%		133.33%		
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				R DR AST TON	נמט	R PH HADI SVIL	S D	RINI	SKC	R PH MAI RSON	s 74	R PH CLIN	741 10MG	R PH ILL IDGE	6 10 1046	E PH	. RG		
				KINSER DRUG STORE 142 EAST CUMBERLAND KINGSTON	300	ROGE 489 LARK	100 D 5M	KROGER PHARMACY 11238 KINGSTON I KNOXVILLE	ATE	KROGER PHARMACY #519 170 E MAIN STREET HENDERSONVILLE	100	425 NOXV	100S ROX ATE	KROGER PHARMACY 380 S ILLINOIS, OAK RIDGE	TAB SMG 100S SKF NIDATE 10MG RG	KROGER PHARMACY 801 MEMORIAL BL' SPRINGFIELD	2 S.K.		
			NOI		50MG 30CC		SOME	~	ENID		10MG		5XG 5XG ENID		ENID		XYCO		
9/6			DESCRIPTION	0383(8395 E ITE	DEMEROL	0387 8904 E ITI	EROL P W/	03877 4560 E ITEM	HYLPI	03888 8295 E ITE	ALIN	0389(8063 E ITE	RITALIN SMG 1008 7410 ROXICET 5MG ROX METHYLPHENIDATE 10MG P	0389! 7301 E ITE	EDR I) HYLPI	0390; 2734 E ITE	P W/		
12/29/9				# K040 ERAG		#- 0 1K129 ERAG	APA	#- 0 K112 ERAG	HET	#- 0 K223 ERAG	RIT	#- 0 K261 ERAG	ROX MET	#- 0 T947 ERAG	DEX	#- 0 K081 ERAG	APA		
006			ITEM #	CUSTOMER#- 003830 DEA #- AKO408395 * = BROKERAGE ITEM	126207	CUSTOMER#- 003876 DEA #- BK1248904 * = BROKERAGE ITEM	126196 DEHEROL 50MG 100S 220300 APAP W/OXYCOD 5MG	CUSTOMER#- 003877 DEA #- BK1124560 * = BROKERAGE ITE	139354 METHYLPHENIDATE	CUSTOMER# - 003888 DEA #- AK2238295 * = BROKERAGE ITEM	101458 RITALIN 10MG 100S 7416 CIBA	CUSTOMER#- 003890 DEA #- AK2618063 * = BROKERAGE ITEM	101457 133813 139356	CUSTOMER#- 003895 DEA #- AT9477301 * = BROKERAGE ITEM	125921 DEXEDRINE TAB SMG 1008 : 139356 METHYLPHENIDATE 10HG RG	CUSTOMER#- 003902 DEA #- BK0812734 * = BROKERAGE ITEM	220300 APAP W/OXYCOD SMG		
GRR900			I	CUS.	1	CUS DEA	пN	CUS DEA	7	CUS' DEA	ā	CUS.	ÄÄÄ	CUS' DEA	ÄÄ	CUS' DEA	7		



VIOLENCE PREVENTION PROCEDURES IN CASE OF ROBBERY

DO

REMEMBER, THE SAFETY OF YOU AND YOUR EMPLOYEES IS THE NUMBER ONE CONCERN.

	-
KEEP becom	IT SHORT AND SMOOTH. The longer the robbery takes, the more nervous the robber nes.
<u>a</u> <u>a</u>	Handle the entire procedure as if you were making a sale to a customer. The average robbery takes less than two minutes.
OBEY	THE ROBBER'S ORDERS. Robbers seldom hurt people who cooperate with them.
000	Let the robber know that you intend to obey. If you are not sure of what the robber is telling you to do, ask. Keep calm and observe what the robber looks like and what he is wearing. Remember exactly what he says.
<u> </u>	Try to get the robber out of the building as soon as possible.
TELL	THE ROBBER ABOUT ANY POSSIBLE SURPRISES.
000	If you must reach for something or move in any way, tell the robber what to expect. If someone is in the cage or vault. If the alarm system must be turned off, tell the robber.
CALI	THE POLICE. Do not hang up until they tell you to do so. Notify the Cardinal Health, Compliance Department as soon as possible.
0	Keep their numbers near the phone. Stay on the phone until they tell you they understand and have all the information they need.
000	Keep at least one line into the division open for incoming calls. Write down a description of the robber and what they said. Protect the crime scene. Discontinue business until the police are finished. Do not touch any evidence.
;	DON'T
DON	T'T ARGUE WITH THE ROBBER.
00	Give him all the cash and merchandise he wants. Remember, the robber has the upper hand — follow instructions.
DON	I'T FIGHT WITH THE ROBBER.
00	The merchandise is not worth risking physical harm. Trying to overtake a robber is foolish, not heroic.
DON	I'T USE WEAPONS.
۵	Weapons breed violence.
DON	NT CHASE THE ROBBER.

You could be mistaken as the robber by the police.

FOIA Confidential Treatment Requested By Cardinal

	First Offense	Second Offense
REGISTRANT OF FENSES		
(COMMERCIAL) COMMITTED KNOWINGLY	Max:	Mann
, = =	1 yr., \$25,000	Max;
	1 71., \$25,000	2 yrs., \$50.000
071155 001155	Max:	Max:
OTHER COMMERCIAL VIOLATIONS	\$25,000	\$50,000
	(civil fine)	(civil fine)
DISTRIBUTION OF I & II SUBSTANCES NOT PURSUANT TO ORDER FORM,		
FALSE RECORDS, COMMUNICATIONS	Max:	` Max:
VIOLATION, ETC.	4 yrs., \$30,000	8 yrs., \$60,000
		77.5., \$60,000
	Max:	Max:
FELONY VIOLATOR AND ORGANIZER	Life, \$100,000	Life, \$200,000
OR LEADER IN CONTINUING CRIMINAL	Profits, Assets	Profits, Assets
ENTERPRISE (SUBSTANTIVE OFFENSE)	Min: 10 yrs.	Min: 20 yrs.
UNLAWFUL DISTRIBUTION, POSSESSION		Max:
WITH INTENT TO DISTRIBUTE, MANU-		30 yrs., \$50,000
FACTURE, ETC. (INCLUDES REGISTR-	Max:	Special Parole:
TRANTS) NARCOTICS IN SCHEDULES I & II	15 yrs., \$25,000	6 yrs.
NONNARCOTIC SCHEDULE I, II AND	***************************************	
ALL III SUBSTANCES	Max:	Max:
THE WOODS PARTIES	5 yrs., \$15,000	10 yrs., \$30,000
	Max:	Max:
SCHEDULE IV SUBSTANCES	3 yrs., \$10,000	6 yrs., \$20,000
	Max:	Max:
SCHEDULE V SUBSTANCES	1 yr., \$5,000	2 yrs., \$10,000
UNLAWFUL IMPORTATION OR EXPOR-		
TATION		
NARCOTICS IN	Max:	Max:
SCHEDULES I & II	15 yrs., \$25,000	30 yrs., \$50,000
NONNARCOTIC SCHEDULE	Max:	Max:
I & II AND ALL III SUBSTANCES	5 yrs., \$15,000	10 yrs., \$30,000
	Max:	Max:
SCHEDULE IV SUBSTANCES	5 yrs., \$15,000	10 yrs., \$30,000
DANGEROUS SPECIAL DRUG OFFENDER WHO (A) IS AN ADULT AND (B) IS CHARGED WITH FELONY, AND 1) HAS TWO CONVICTIONS AND HAS SERVED ME IN PRISON, OR 2) DEALS REG-	Max:	
JLARLY FOR PROFIT OR 3) IS AN	25 yrs. Same	None
RGANIZER OF CONSPIRACY. (SEN- ENCING PROVISION)	fine otherwise prescribed	
SIMPLE POSSESSION OR DISTRIBUTION OF ANY		
CONTROLLED SUBSTANCE FOR NO		
	Max:	Max:

PAGE 1		DEA # AN8966840 AN8966840	DEA #	BK2565022 AH8966840 AH8966840 AH7152197 AH8966840	TEXT-EXPIRED MERCHANDISE TEXT-CUSTOMER RETURN
NSSINC. SELECTED ITEM AUDIT REPORT YR 100UD C4 100 EA EA VENDOR-11860 UDL LABORATORIES DEA#- PO BOX 10319 ROCKFORD, IL 611313019	DATE REC DEA # JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA 019616 7/12/95 JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA 019616 7/20/95 JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA 019616 8/07/95 JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA 019616 8/09/95 CARDINAL SYRACUSE, 6012 MOLLOY ROAD, SYRACUSE, NY 13211	CRD DATE CUSTOMER 8/03/95 ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO 63376 8/10/95 ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO 63376	CUSTOMER	HIGH DESERT MEDICAL GROUP, 43845 N 10TH ST WEST, STE 2B, LANCASTER, CA 93534 ROBERT E HAWKINS DAD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO 63376 ROBERT E HAWKINS DAD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO 63376 JAMES WILLHOF CLINIC, 190 HEDICAL CENTER DRIVE, WOODRUFF, SC 293881 JAMES WILLHOF CLINIC, 100 HEDICAL CENTER DRIVE, WOODRUFF, SC 293881 JAMES WILLHOF CLINIC, 100 HEDICAL CENTER DRIVE, WOODRUFF, SC 293881 ROBERT E HAWKINS DAD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO 63376	2/24/95 ADJUSTMENT CODE- MINUS VERIFICATION 8/03/95 ADJUSTMENT CODE- CREDIT RETURNS AUTHORIZED SCRP TEXT-C
IYD 500MG	TO-11/02 IX REC DA	VEND CUST		11 RO 11 LO 11 CA 12 CA 12 CA 13 CA 14 CA 15 CA 16 CA 17 CA	9 DATE- 1 DATE-
.05 11/02/95 S EM-035530 CHLORAL HYD 500MG SYR 100UD	EIVED FROM- 1/01/95 TO-11/02/95 P.O. # QTY OND QTY REC DATE 1479400 1 7/12 1491400 1 7/20 154600 2 2 8/09	TOCK 1	USTOMER SALES VOICE SHIP DATE QIY	46168 95/01/04 67384 95/07/13 60331 95/06/30 74154 95/07/24 83528 95/08/08 81569 95/08/03	ADJUSTHENTS QUANTITY- QUANTITY-

EXHIBIT J

CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION WASHINGTON, D.C. 20537

throlled Substances Act or serie reads in perties follows: 304. (a) A registration pursuant to section 382 to manutacture, distribute.

documes a commission substance may be autoended or revolved by me Atomey General upon a finding that the registrance

this tole or side III,

(2) has been convicted of a fetony under the title or side III or any other law of the United States, or of any State, researing to any substance.

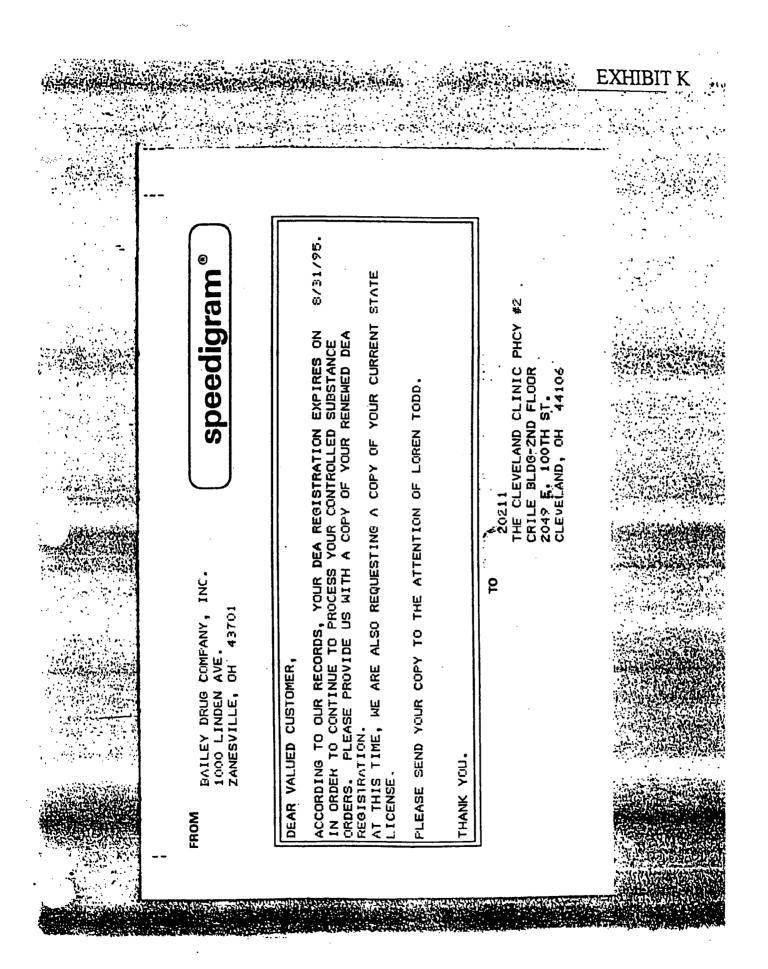
(3) has had his State some or registration suspended, revoked, or denied by competent State authority and is no longer aumorized by State tary to engage in the manufacturing distribution, or depending of controlled automances.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE_PAID
PW0191685	05-31-96	\$438.00
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,3,3N,4,5	CDISTRIBUTOR	04-20-95

WHITMIRE DISTRIBUTION CORP DBA CARDINAL HEALTH 3530 PAN AMERICAN FWY NE ALSUQUERQUE, NM

871C7

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.



December 1, 1995

DEAR VALUED CUSTOMER:

Our records indicate that your D.E.A. Registration Certificate expires as of

Please provide us with a copy of your current Registration Certificate as soon as possible to avoid service interruption of Controlled Substance Items.

A self-addressed envelope is enclosed for your convenience.

Thank you in advance for your prompt attention to this matter.

Sincerely,

Division Manager

CARDINAL HEALTH DEA REGISTRATION VERIFICATION FORM

DEA CONTROLLED SUBSTANCE	S REGISTRATION CERTIFICATE
Customer Name:	
Address:	
·	<u>. </u>
	·
Registration Number:/_	
Two letter	r prefix Seven letter suffix
Expiration Date:	
•	
(Circle permitted schedules	s 2 2N 3 3N 4 5)
	
STATE REGISTRATI	ON CERTIFICATE
Registration (License) Number:	
expiration Date:	

EXHIBIT M

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CUSTOMER	ADDRESS	2711 OLD SAVANNAH RDA		P. O. BOX 388	2303 SKIDAWAY ROAD	1429 NEWCASTLE ST.	122 S JEFFERSON ST	9 S. FOREST AVE.	3105 BEACH BLVD.	103 PROFESSIONAL CTR	413 MEMORIAL AVE.	3365 TAMERA LANE	217 MAIN STREET	101 SOUTH MAIN STREET	104-A SOUTHEAST BROAD	DRUG CO.	2750 SPEISSEGGER	(BILL TO ONLY)	BROOKS ST	SAVAGE RUAD	1200 WOODRUFF RD. UNI	116 WEST RICHARDSON A	9143 PHILLIPS HIGHWAY	S. FALMELIO AVE.	AND A PROPERTY OF THE PROPERTY	1200 GREENVICE FIGUR		373 WASHINGTON STREET		P. O. BOX 219	ASST IS CLOSED	9440-3 PHILLIPS HWY	9-F HUNIER KD.	S BETACK BOLDEN ACT		•	CLINIC		3624 J. DEWEY GRAY CI		554-D. MEMORIAL DR EXT	62 CHESTNUT STREET	265 KING ST	D/B/A COMPREHENSIVE	306 MAIN STREE!	AND HOUSELIAL CIR. BLVD		2441 WHISKEY ROAD SOU	
AVANNAH	CUSTOMER	SOUTHSIDE PHARMACY	SCOTT'S PHARMACY	SMITH'S DRUG STORE	SAUERS DRUG STORE	ROCERS DRUG STORE	STRANGE DRUG CO	SCOTTLE DISCOUNT DRUG	ST NICHOLAS PHARMACY	PROFESSIONAL PHARMACY	: =	LIT - RUN PHARMACY	WRIGHT'S DRUG STORE	α.	>	BERKELEY PORT CITY	q.	T-2 MEDICAL, INC.	CLARENDON DRUGS, INC.	CAREMARK PHARMACY SER	CAREMARK INC.		PHARMACY	DANIEL'S PALMETIU PHA	DOCTOR'S MED SUPPLY &	DARYL'S DISCOUNT DRUG	ECKERD'S #Z/10	CONTRACTOR SECULAR SEC	CATEURY PHARMACY	HAILEY'S DRUG STORE	HARDEN'S PHARMACY	HEALTH INFUSION INC.	ISLAND PHCY SERVICES	INMAN DROGS INC.	INFOSION THERATIES	CHA SERVICE		JOHN BECK PHARM. SERV	WESTSIDE PHARMACY	LIFELINE PHARMACY	MCLESKY TODD DRUG	MADDEN'S PRESC. SHOP	SCOTTIE DISCOUNT DRUG	KIMBERLY QUALITY CARE	MAIN STREET PHARMACY	MEDICAL PAVILION PHCY	ARE PHAR	FIAN I BUN #104	
CAPDINAL P	# TSOO	02955-0	18062-0	18074-0	02800-0	0-01220	11360-0	18065-0	03795-0	00550	03030	18297-0	03220-0	18289-0	17020-0	17094-0	17063-0	05360-0	17255-0	01481-1	01482-2	17666-0	01480-0	01725-0	01750-0	01720-0	10439-0	מיילים מיילים מיילים	17513-0	17491-0	10626-0	02048-8	17563-0	02130-0	10402-0	17633-0	03589-0	17634-0	02226-0	10803-0	17791-0	17743-0	11277-0	02272-0	02294-0	02416-0	02480-0	02363-0	1

		verse of PUR apy for Instru	No orde	order form may be issued for Schedule 1 and II substances un aplated application form has been received, (21 CFR 1305.04).									144 &		OMB A	PPROVAL 7-0010		
O:	(Name of	Suppliers			STREET ADDRESS													
		W. DALY,	INC.					11 CENTENNIAL DRIVE										
	and ST		•	DA.	TE			TO BE FILLED IN BY SUPPLIER										
P	EABOD	Y, MA 019				6/92		SUPPLIERS DEA REGISTRATION No.										
TO BE FILLED IN BY PURCH																		
	No. of Packages	Size of Package		Name of Item) 					Netic	inal Di	rug Ca	ode			Packages Shipped	Date Shoped	
ı	1	100	PERCODAN	XXXX	TABS					ΊI	L		1		! i	1	Ī .	
2	1	500	PERCOCET	NNN	TABS	5/325		Ш	1	11				Ī				
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R	ETL	PHARMACY	922380	221														
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Dosage	Limit
<u>spital</u>	<u>Retail</u>
Tabs	400 tab
bs/Spans	800 Tabs/S

Product	Strength	Hospital	<u>Retail</u>
Codeine Sulf	All	800 Tabs	400 tabs
Dextroamphetamine	. 11	- 00 - 1 - 1 -	
(Dexedrine, Dextrastat)	All	700 Tabs/Spans	800 Tabs/Spans
Desoxyn	All	300 Tabs/Grad	500 Tabs/Grad
Hydromorphone (Dilaudid)	All	900 Tabs	500 Tabs
Methadone (Dolophine)	All	2000 Tabs	700 Tabs
Meperidine			
(Demerol, Meprozine,	All	600 Tabs	400 Tabs
Mepergan Fortis)			
Methlyphenidate (Ritalin)	All	800 Tabs	800 Tabs
Morphine Sulfate (MS			
Contin, MSIR, Oramorph)	Ali	600 Tabs	500 Tabs
Oxycodone/Acet			
(Tylox, Roxilox, Roxicet,	All	3800 Tabs/Caps	1200 Tabs/Caps
Percocet, Endocet)			
Oxycodone/Asa			
(Percodan, Endodan,	All	500 Tabs	500 Tabs
Roxiprin)			
Oxycodone	All	800 Tabs	600 Taka
(Oxcontin, Roxicodone)	All	oud Taus	600 Tabs

Dosage Limit

Product	Strength	Hospital	<u>Retail</u>
Acetamenophen w/Cod (Tylenol w/Cod, Phenaphen)	All	1400 Tabs	1300 Tabs
Alprazolam (Xanax)	All	1400 Tabs	2500 Tabs
Butalbital Compound (Florinal w/Cod, Fiortal, Fioricet w/ Cod)	All	500 Tabs/Caps	500 Tabs/Caps
Aspirin w/Cod	All	300 Tabs	400 Tabs
Clorazephate (Klonopin)	All	1000 Tabs	800 Tabs
Clorazephate (Tranxene)	All	700 Tabs	1300 Tabs
Diazepam (Valium)	All	1000 Tabs	2500 Tabs
Dexfenfluramine (Redux)	AlI	400 Caps	500 Caps
Diphenoxylt/Atropine (Lomotil, Lonox)	All	1600 Tabs	7500 Tabs
Dronabinol (Marinol)	All	300 Tabs	400 Tabs
Fenfluramine HCL (Pondimin)	All	800 Tabs	1700 Tabs
Hydrocodone (Anexsia, Dolaset, Hydrocet, Hycodan, Hyphen, Lorcet, Lortab, Zydone, Vicodin)	AlI	1200 Tabs/Caps	800 Tabs/Caps
Lorazepam (Ativan)	All	1200 Tabs	2400 Tabs
Meprobamate (Miltown, Equanil)	All	600 Tabs	1400 Tabs
Phentermine (Ionamin, Fastin, Adipex-P)	All	600 Tabs	1100 Tabs
Pentazoline (Talwin, Talacen)	All	700 Tabs	700 Tabs
Propoxyphene (Darvon, Darvocet, Propacet)	All	1100 Tabs	1900 Tabs
Temazepam (Restoril)	All	700 Caps	800 Tabs

Exhibit Q

Error Correction

In the following examples, assume the worst case — the order was shipped to the customer. Also assume the shelf count confirms the error.

Although these examples only address shipping errors involving Schedule II controlled substances, certain portions of the corrective action processes also apply to shipping errors involving Schedule III-V controlled substances which must be handled in a similar fashion.

Example 1: A customer orders Ritalin 5mg 100. The order is keyed as Ritalin 10mg 100. The order filler picks Ritalin 10mg 100. Customer receives and is invoiced for the wrong item.

Corrective Action:

- Request the customer submit a blank for the mispicked item (Ritalin 10mg 100). Have the customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record the actual ship date, change the blank number in the ARCOS record. The blank number cannot be changed on the invoice.
- Key in the original blank with the correct item (Ritalin 5mg 100). Pick, bill, and ship the product. Attach a legible statement, preferably typed, to the original blank which reflects the correct NDC, ship quantity and date. Create an invoice and ARCOS record for the correct item.
- If the customer wants to return the mispicked item (Ritalin 10mg 100), issue a blank to the customer to buy back the product. Upon receipt, issue credit to customer.

Example 2: A customer orders Ritalin 5mg 100. The order is keyed as Ritalin 5mg 100. The order filler picks Ritalin 10mg 100. Customer gets wrong item, but is invoiced for the right item.

Corrective Action:

- Have the customer submit a blank for the mispicked item (Ritalin 10mg 100). Have the customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record the actual ship date. Key in an order for the mispicked item (Ritalin 10mg 100), but do not ship the product. The customer will receive an invoice, but no product.
- Ship the correct product (Ritalin 5mg 100) from the original blank. The customer will get product, but no invoice.
- Change the ship dates of the products in the ARCOS records. The original invoice cannot be changed to reflect the actual ship date.

ERRORS.doc 5/25/99

 If the customer wants to return the mispicked item (Ritalin 10mg 100), issue a blank to the customer to buy back the product. Upon receipt, issue credit to the customer.

Example 3: A customer orders 5xRitalin 5mg 100. The order is keyed as 10xRitalin 5mg 100. The order filler picks 10xRitalin 5mg 100. Customer was billed for and received more than what he ordered.

Corrective Action:

- Request the customer submit a blank for the additional product. Have customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record actual ship date of product.
- Correct the ARCOS record to show correct ship quantity for original blank. The blank number and ship quantity cannot be changed on the invoice. Create another ARCOS record to show ship quantity, date, and blank number of overshipment.
- Correct the ship quantity on the original blank by drawing a line through the incorrect quantity and entering the correct quantity.
- If the customer wants to return the extra product, issue a blank to the customer. Upon receipt of the overshipment, issue credit to the customer.

Example 4: A customer orders 5xRitalin 5mg 100. The order is keyed as 5xRitalin 5mg 100. The order filler picks 10xRitalin 5mg 100. Customer received more than what he ordered or was billed.

- Request the customer submit a blank for the additional product. Have customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record the actual ship date of the product.
- Key in an order for the overshipment, but do not ship product.
 Reference the actual ship date in the text field of the order.
- Modify the ARCOS record to show the correct ship date of the product.

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United States Department of Justice Drug Enforcement Administration Office of Diversion Control Suspicious Orders Task Force



EXHIBIT II

SUSPICIOUS ORDER REPORTING SYSTEM OF 1998 For Use in automated tracking systems

The Current Calculation Being Used for List I Chemicals and Schedule II - V Controlled Substances

Terms & Definitions

This formula is used to calculate the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious.

- Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.
- 2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero).
- 3) Divide total quantity purchased by the total customer months.
- 4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.
 - Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III N-V Controlled Substances and non-Controlled OTC products containing List I chemical items.
- At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycles times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

SOTF Report Appendix A: 4

FOIA Confidential Treatment Requested By Cardinal



DEA COMPLIANCE MANUAL

APPENDIX E

Methamphetamine Control Act Products

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COLD PREP LIQ 60Z COLD TB 16 COLD TB 32	2585420 GUAIATUSSIN CF SR 120ML	N CCF TB 50	1096015 CHERACOL PLUS EL 40Z	2303436 LIQUI-HISTINE-D EL 160Z	2303410 LIQUI-HISTINE DM EL 160Z	TENYL EL 120ML	2181352 GUAIFENESIN CF SR 120MI	2181345 GUAIFENESIN/CF SYRUP 80Z	2181287 TUSSAMINIC/GUAIF SR 40Z	IINIC/GUAIF SYRUP	2181311 TUSSAMINIC/CPM SR 40Z	2181261 TLISSAMINICOL SYRIP ACT	2139756 ALTARUSSN CF SR 120ML	SSIN CF SR 80Z	2706547 ALTAMINIC SR 4OZ COLD/ALLERGY AL	2706539 ALTAMINIC SR 80Z COLD/ALLERGY AL	2139/38 ALIAMINIC DM COUGH SK 120ML 2139830 ALTATAPP FL 407	P EL 240ML	P EL 480ML	P EL 2MG 3840ML	NI EX 802 A/F	P EL 402 A/F	2539435 MYTUSSIN CF COUGH SR 120M 2539427 MYTI ISSIN CF COLIGH SP 246N	APP AF EL 40Z	Ę.	-	ZOML		SR ORANGE 40Z	SR 80Z ORNG	FCONGEST 107 4	2445997 SPEC T DECONGESTANT LZ 16 BRL	2202935 GENAMIN COLD SYR 40Z SEE 1031053	EX NF 40Z	TANT D TB 1000	1498310 DRISTAN TB TIN 12X12 MULTI SYMP	494392 PHENYLPROPANOL HCL TB	BROMATABBEL 240ML SF HLS	DIMAPHEN EL 480ML		3 TB 1000	1003177 ACUTRIM LATE DAY TB 20 014317	1005 195 ACUTRIM LATE DAT 16 40 01455/ 1396753 ACUTRIM II TB 20 MAX-STRN
2610871 666 COLD PREP 2610897 666 COLD TB 16 2610905 666 COLD TB 32	2585420 GUAIATI	2296051 GELPIRIN CCF TB 50	1096015 CHERAC	2303436 LIQUI-HI	2303410 LIQUI-HI	2181386 BKUMPHENYL EL 120ML 2181378 BROMPHENYL EL 807	2181352 GUAIFEN	2181345 GUAIFEN	2181287 TUSSAM	2181279 TUSSAM	2181311 TUSSAM	2181261 TUSSAM	2139756 ALTARU	2706562 ALTARUSSIN CF SR BOZ	2706547 ALTAMIN	2706539 ALTAMIN	2139/38 ALIAMINIC UM CO	2139707 ALTATAPP EL 240ML	2277374 ALTATAPP EL	2301075 ALTATAPP EL 2MG 3840M	2706513 ALTORANT EX 802 AF	2706638 ALTATAPP EL 402 A/F	2539435 MYTUSS	2539260 MYPHETAPP AF EL 40Z	2580975 MYPHETAPP AF EL 240	2504132 DIMETAPP EL 120ML	2214765 COLD&ALLERGY EL 120M	2214617 COUGH EX 40Z YLW	2214591 COUGH SR ORANGE 40Z	2214583 COUGH SR 80Z ORNG	2282473 COLDLOC LICUID EX 1602 1047166 SPEC T DECONGEST 1 OZ	2445997 SPEC T D	2202935 GENAMIN	2202927 GENAMIN EX NF 402	2209427 CONGESTANT D TB 1000	1498310 DRISTAN	1494392 PHENYLP	2212378 DROMALAPPEL 240ML SP	2204618 DIMAPHE	2711117-SINUSTAB TB 100	2711125 SINUSTAB TB 1000	1003177 ACUTRIM	1396753 ACUTRIM
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R MONTICELLO DRUG MONTICELLO DRUG MONTICELLO DRUG	HI-TECH	•	ROBERTS PHARMACEUTICAL ROBERTS PHARMACEUTICAL	LIQUIPHARM	LIQUIPHARM	A V V V V	MOVA		•		MOVA		ALTAIRE	ALTAIRE	ALTAIRE	ALTAIRE	ALTAIRE	ALTAIRE	ALTAIRE	ALIAIRE	ALTAIRE	ALTAIRE	MORTON GROVE PHARMACEUTICALS	MORTON GROVE PHARMACEUTICALS	MORTON GROVE PHARMACEUTICALS	KING PHARMA			REXALL MANAGED CARE	REXALL MANAGED CARE		,	GOLDLINE	GOLULINE	RUGBY	WHITEHALL ROBINS HEALTHCARE	URL	HALSEY DRUG	MAJOR PHARMACEUTICALS	DIXON-SHANE		CIBA SELF MEDICATION	
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1396779 ACUTRIM II TB 40 MAX-SITRN 2048494 ACUTRIM TB 75MG 20 16-HR 018817	1048503 ACUTRIM TB 75MG 40 16-HR	2149177 DIETRIM ES TB 20 QLT	2474393 MEGA-TRIM CL 40 MJR	13/8148 OURINEX SUPER TAB 508	1505692 THINZ SPAN DIFT CAPS 21S WMS		1254705 PERMATHENE TRL DIET CAP 48S	1495449 UNI-SLIM CAP 20S URL	TAB 10	2256279 LDR COLD CAPS 20CT	2313021 LDR TRIACTING SYRUP 40Z 11026	2313005 LDR TRIACTING MULT-SYMP 4OZ 14526	2312999 LDR TRIACTING EXPECT 40Z 1822B	1783430 LDR BRONATAPP EXT RLF TAB 24CT	2312981 LDR PSEUDO COLD & ALLERGY TB 24CT	1376375 LDR COLD CAPS 10CT	1783448 LDR EFF COLD I AB 2001 48460	9949094 I DO ALL COURT DIAGOT BEATS	17581421 DB COLD & COLD DM ELIXIB 407	12391851 DR COLD & ALLERGY ELIX 40Z	2302933 LDR TUSSIN CF SR 802	1833789 ROBITUSSIN-CF SR 120Z	:	1300/22 PROPAGEST 18 100 CRN	2195683 THREAMINE EXP PT NAT	1158211 BROMALINE OTC EL 3840ML RUG	1395078 TRI-DEC PED DR 10Z RG	1394782 TRI-DEC CHILD SR 40Z RUG	1185842 BROMALINE ORAL SL 480ML 1649946 TRIPHENICOLD MILL TI SVM I 0 407 R10	1325760 BROMALINE PLUS TABS 24 RG	1624949 COLD TAB 100S W/EXPECT RG	2163673 DIMAPHEN TB 12 MJR	≥. ; ;	2164450 THERA-HIST SK 40Z MJR	_		1488519 SINAPILS TB 36 PFR	PFR.	14085333 IN-NETRIN AS IAB 243 FFK			2032712, Hydromint SR 25 mg 1602	1843390 UN Timed Cold CP 10	1842756 UN Tristine SR 120 ML	1842558 UN Instine EX 120 ML	1999036 Rhinex D-Lay SA 100	2053627 Rhinex D-Lay SA Tab 1000	1479567: Tri-Phenmine 480 ML	2639573 Cold and Allergy 120 ml	
159840 20974	20882	872938	371904	474401	331805	4904	12802	593087	915645	968722	928330	928283	928275	968633	933481	17843	803303	900/49	927244	968684				70002	735493	652407	771627	771635	861847	680940	839582	675520	598750	749370	698741	710555	935298	935298	88072	423416	569755		\\ \ \	•	7. 466948		577928	127663	757209	
CIBA SELF MEDICATION CIBA SELF MEDICATION	CR CIBA SELF MEDICATION			FOX PHARMACAL INC		••••	ALLEGHANY	URL	NAT-RUL HEALTH PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND TROUGES	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	LEADER BRAND PRODUCTS	WHITEHALL ROBINS HEALTHCARE	WHITEHALL ROBINS HEALTHCARE	CAKNECK	BARRE-NATIONAL	RUGBY	RUGBY	RUGBY	RUGBY	RUGBY	RUGBY	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	PFEIFER		Preirren Boberts Pharmace Itical	KING PHARMA	WARNER CHILCOTT	WARNER CHILCOTT	AMERICAN PHARMACEUTICAL CO	AMERICAN PHARMACEUTICAL CO	AMERICAN PHARMACEULICAL CO	GATE	GATE	GOLDLINE	GOLDLINE	
75MG (75MG ES	75MG CR	SMC2	75MG TR				DET	8-75 TR	1-6.25/5	MULT-	EXPECT	12-75 ER	12-75 ER	8-75 CR	KELIEF	מאמע באם א	2	2-12.5/5	 	P.	<u>ن</u> ا	5WCZ		2-12.5/5	PED	PED	2-12.5/5 MIII T.	PIUS	EXPECT	TIMED	2 40 616	2-12-5/5	2-12.5/5	2-12.5/5			:	2-12.5/5	25-5/5ML	PED	4-75 CR	2-12.5/5	֡֝֟֝֟֝֟֝֟֝֟֝֟֝֟֝֟֝֟֝֟֟֝֟֟֝֟֟֝֟֟֝֟֝֟֝֟֟֝֟	W.	Š	PED		
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83014537 83018817	83018837	603013609	904243639	1042500201	7295916021	7386569126	7386574800	677123660	9460431710	37205010960	37205011626	37205014026	37205018226	37205030662	37205045162	37205048252	3720505049450	37205050173	37205093998	37205094426	37205096534	31867722	31867725	47207120	472156216	536039090	536219275	536219397	536264585	536338935	536497901	904021412	904021624	904033120	904071320	904071328	927003363	927013363		60793000708				:	84060904		:_	0	182606537	
		00603-0136-09	00904-2436-39	10425-00201	72959-16021			00677-1236-60	94604-31710	37205-0109-60	37205-0116-26	37205-0140-26	37205-0182-26	37205-0306-62			37205 0504 72				37205-0965-34	****		00.050-0051-10 00472-0712-04		-			00536-2345-85 00536-2682-97				-	00904-0331-20				00927-0133-63			00047-2917-23				00084-0009-04				00182-6065-37	

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	in clinical descriptions of the second of th	Pediacon DX Chil 120 ml	2633352 Histafed Ped OTC 120 ml	2017580 Respinol LA 100	4000000 Treson Di 400		Zbbab45, S-1 Forte 120 ML	2665552: S-T Forte 240 ml	2665560 S-T Forte 480 ML	2665578 S-T Forte 3840 ML	2665586 S-T Forte SF 120 MI		TWO OFF THE PLANT OF THE PROPERTY OF THE PROPE	Zuu1550i Bromanare 480 ML	2668051 Bromaline Instpk. 180 ml	1990167 Nasahist 100	1709252 Tusnuelin 280 ml		2703073 Do Tues TTT 400	100 LINE 100	27040Z Demistrae UM 111 480 ML	2/015/1 Metahistine D EL TTT 480 ML	2623486 Dimaphen 100	2638872 Anti-Allergy MED 37.5/4 20			2624674 Norphanamine SA 100	2621183 Lantuss Forte SA 100	2621191 lantuss XP 480 ml	2677748 Phentex 280 ML	2677839 Tri-fedrine 120 ml	2677821 Tri-fedrine 402	2677847 Tri-Fedricol 120 ml	2677649 Nalphen DX Pediactric 30 ml	2677656 Nalphen EX Pedicatric 30 ml	2677672 Nalphen 480 ml	2677680 Naiphen 3840 MI	2677524 Nalphen Pediatric 120 ml	2677532 Nalphen Pedicatric 480 ml	2677540 Nalphen Pediatric SR 3840 ml	2677664 Natphen Pediatric 30 ml		1792902 T-Koff 480 ML	2620896 Codegest 480 ML	2620904 Codegest 3480 ML	2678084 Guaifenesin/Phenyl P 400/75 100	2696730 PPA +Gualfenesin SA 400/75 100	2678092 Guaifenesin/Phenyl P 400/75 100	2678695 Brompheniramine/PP 120 ml	2678704 Brompheniramine/PP 240 mi	2678712 Brompheniramine/PP 480 ml	2678720 Brompheniramine/PP 3840 ml	2678795 Biotuss CR 120 ml	2678803 Biotuss CR 240 ml	2508976 MOTRIN IB SINUS TB 30	2508992 MOTRIN IB SINUS CP 30	2431260 TYLENOL GELTAB A/S 24 50424	2489755 TYLENOL CHILDRENS EL 402 FLU	2191260 GENAPAP COLD GELCAP 20S GL	1045616 ALLEREST SPF TB 20 B1G1F 059202	2168441 ALLERFRIN SYRUP 1280Z OTC RG	1494525 PHENAPAP/SINUS TAB 30S RG		
	_	863033	725250	480584	373306	27.3500	8201/8	830186	830194	830259	830267	830075	2000	2/200/2	869678	366234	197319	RZOTAR	860651	07070	08/0/0	644217	666432	749060	707155	299760	675547	655147	655155	897680	897990	897981	898040	897515	897523	897540	897558	897388	897396	897400	897531	698156	271233	654280	624299	898600	763276	898651	899895	899909	899925	899933	090006	280006		472875	250791	449687	885100	3577	487473	415634		
No O	_	E GOLDLINE	GERIATRIC	MISEMER	MISEMED	MISCHIEN COOT THOSEN	SCOI-103SIN	,	SCOT-TUSSIN	SCOT-TUSSIN	SCOT-TUSSIN	SCOLTIBEIN	SOCIETORIAL	BARRE-IVALIONAL	RUGBY	KEENE	CIRCLE	HI MOORE	H MOORE	10001		H L MOOKE	MAJOK PHAKMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	COLUMBIA DRUG	COLUMBIA DRUG	HI-TECH	HI-TECH	H-TECH	H-TECH	H-TECH	HI-TECH	HI-TECH	H-TECH	HI-TECH	HI-TECH	H-TECH	HI-TECH	POLY PHARMACEUTICALS	T E WILLIAMS	GREAT SOUTHERN LABS	GREAT SOUTHERN LABS	75-400MG INTERPHARM	75-400MG:INI ERPHARM	5-400MG IN ERPHARM	BIO-PHARM	BIO-PHARM	BIO-PHARM	BIO-PHARM	BIO-PHARM	BIO-PHARM	PHARMACIA & UPJOHN CONSUMER	PHARMACIA & UPJOHN CONSUMER	MCNEIL CONSUMER	MONEIL CONSUMER	GOLDLINE	CIBA SELF MEDICATION	RUGBY	RUGBY	1	Page 9
	misc1	CHILDRE	PED	ñ	2		450c/A	W/SUGA	-W/SUGA	W/SUGA					2-12.5/5	స్ట		Č	Š	2	-	#NAME!	: -1-		FORMUL	2-12.5/5	ž.	- 14.7 14			1-6.25/5	6.25-50		PED	PED			PEO		PED	PED		:	:	_;	75-400MG	75-400MG	75-400MG	2-12.5/5	2-12.5/5	2-12.5/5	2-12.5/5			SINUS	SINUS	SINUS	CHILD	. 1,100	SINUS	1.25-30	HA/CONG RUGBY		
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RUG	493972 UNI-COACE TAB 24S URL	494442 SINUS TAB NON-DROWSY FORM 100 URL	207216 EFFERVES COLD MED 36S	2516706 MAPAP SINIIS CP 24 MS MIR	595230 MOTRIN IB SINUS TAB 20S UPJ	CPLT 20S			357524 DIMACOL COUGH & COLD CAPLET 24S		913391 DIMETAPP CONGEST LIQUIGEL 12S AHR	913383 UIME LAPP CONGEST LIQUIGEL 24	668185 DIMETAPP SINIS 40S 2280-55	2224012 DIMETAPP DECONGEST PEDI 15ML	878891 ROBITUSSIN CGH/CLD LIQ-GEL 12S	879147 ROBITUSSIN CGH/CLD LIQ-GEL 20S	ROBITUSSIN SEV CONG LIQUICAP 12	2238780 BOBITHSON OF MODELLI MODEL 426	ROBITUSSIN CLD/CGH/FLU L/GEL	2428258 ROBITUSSIN NT CP 20 LIQUIGEL	1243468 THERAFLU M/S NON DROWSY 6S	1379320 PEDIACARE CGH/CLD TAB 16S CHEW	1013184 TYLENOL COLD TAB 24S 172-24	1013200 TYLENOL COLD TAB 50S 0172-50	:0.(0		1053560 SINE-AID CAPLET XS 243 19124	CLD SEVERE CONGESTION	2489748 TYLENOL CLD SEVERE CONGESTION 24	1055420 TYLENOL COLD CAPLET 50S 285-50	2186856 TYLENOL SINUS GELTAB 24S	TYLENOL	4906197 SINE AID CAP! ET IB 206 20020 MCN	PEDIACARE COLD/ALLERGY TA	124734 SINE-AID GELCAP MAX STR 20S	124924 SINE AID GELCAP MAX STR 40S	855584 I YLENOL ALLERGY SINUS GELCAP 20S			2190023 TYLENOL CHILD CLD+CGH CHEW 24S	TYLENOL	1053586 TYLENOL MS SINUS CAPLET 60S	COLOGAPIET 24S NO	535327 TYLENOL COLD CAPLET 50S NO	SINUS CAPLT	282185 TYLENOL ALLERGY SINUS CAPLT 50S
783668	592579	428124	10102			883590	883620	545232	545260	545279	349020	801054	801062		-		856655			248169 2		738557			550990 2	-			443778 24				865249	_			718845	- -	 			431346 10				634891 12
RUGBY			CUMBERLAND-SWAN, INC	MAJOR PHARMACEUTICALS	PHARMACIA & UPJOHN CONSUMER	PHARMACIA & UPJOHN CONSUMER	PHARMACIA & UPJOHN CONSUMER	WHITEHALL ROBINS HEALTHCARE	WHILEHALL ROBINS HEALTHCAKE	WHITEHALL ROBINS HEALTHCARE	WHITEHALL ROBINS HEALTHCARE	ROBINS CONS	ROBINS CONS	WHITEHALL ROBINS HEALTHCARE		ROBINS	WHITEHALL ROBINS HEALTHCARE	WHITEHALL ROBINS HEALTHCARE	WHITEHALL ROBINS HEALTHCARE	WHITEHALL ROBINS HEALTHCARE	NOVARTIS CONS	MCNEIL CONSUMER		MCNEIL CONSUMER	EIL CONSUMER				EIL CONSUMER			EIL CONSUMER				EIL CONSUMER			<u>_</u>		: ٰ⊑	FIL CONSUMER				EIL CONSUMER
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717446 DRIXORAL TAB 20S NO DROW 508-02	IRONOTB 100 55502	ALLERGY SINUS 12	ALLERGY SINUS 24	563005 DRIXORAL ALLRGY/SIN TB 72/2 TRLSZ	1903ZUB CHLUR-I KIM CAP 4HR 24S NUROW PL	931-01	931-02	034-03	ARCONG CAPS 108	OO CNP	2159457 NASAL DECONGESTNT ANTIHIST TAB24S	2159523 ANTIHISTAMINE TAB 12 HR TIMED 10S	2/D 6PK RXC	158962 SINUS RELIEF PLUS TB 24 RXC	RANTHIST TR 20 GLD	1038926 GOLDLINE 12HR ANTIHIST TB 10 GLD	PSEUDOEPHED HCL TB 60MG 100UD GLD	30MG 100 GLD			JS TB 24 GLD		3.0	1720929 TRIPROLIDINE/P-EPHED TB 100 GLD	P-EPHED TB 1000 GLD	24 GLD	JGH MED 6 7035-87 GL	4 B1G1F SEE1212836	8 MAX-STRN	2 MAX-STRN	TB 20 059202	OND SEE148432	STR TB 24 062401	262260 SINAREST TAB NO DROWSY 20S 063056	20S 117901	FINE TAB CONTOACH CUN	RUG	8	:	MOTORIST RIG	B _B		چ ا		243542 PSEUDOEPHED HCL TB 30MG 100 RUG	HCL TB 30MG 1000 RUG	HCL TB 30MG 24 RUG	DT TB 100 RUG
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651168	77577	687413	687421	256300	77186	687375	687383	687391	532410	438251	655740	655651	750000	768685	694843	215562	886548	128562	128554	669415	128570	128376	584766	353388	398705	914509	728055	741698	747262	679470	281840	3579 582026	140635	478822	140910	444375	681350	523410	376000	006669	708267	782637	708259	415642	609870	683302	683299	708607
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SCHERING-PLOUGH			SCHERING-PLOUGH	SCHERING-PLOUGH	SCHEBING-PI OF IGH	SCHERING-PLOUGH	SCHERING-PLOUGH	SCHERING-PLOUGH						MEXALL WARD			GOLDLINE	GOLDLINE	GOLDLINE	GOLDLINE		•• ••					GOLDLINE	CIBA SELF MEDICATION	ICIBA SELF MEDICATION	CIBA SELF MEDICATION	CIBA SELF MEDICATION	CIBA SELF MEDICATION	CIBA SELF MEDICATION	CIBA SELF MEDICATION	CIBA SELF MEDICATION		RUGBY		RUGBY		RUGBY	RUGBY		RUGBY		RUGBÝ	RUGBY	RUGBY
120MG	6-120 CF	6-120 CR	6-120 CF	2021-0	Apr-60	120MG	120MG	120MG	CGH/CON	Apr-60	2.5-60MG		MEDICIN	PLUS 2 FANNO	6-120 CR	·O	60MG	30MG	30MG	SOMG	75-60MG	2.5-60MG			MAX-STR		MEDICIN	MAX-ST	MAX-ST	MAX-ST	SINIS	2.0	HEADAC			60MG	1.25-30	Apr-60	2.5-60MG	2.5-60MG		•		DACONG TAYOUND	30MG	30MG	30MG	60MG
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The state of the s	862 NASAL DECON PL TAB	2450278 COLD RELIEF NF TB 50	1590298 AUVIL COLD & SINUS CPLT 20S 18010	1944010 ADVIL COLD & SINUS I AB 205 18510	1944020 ADVIL COLDADINOS 1B 40 1404854 DBISTAN COLD CAB SAS MIDBOW143034	1404847 DRISTAN COLD CP 40 M/D	1661990 DRISTAN JUICE MIX-IN 5S 123020	1661982: DRISTAN JUICE MIX-IN 10S 1230-30	2428266 DRISTAN COLD&COUGH CP 20 LIQUIGEL	1066711 DRISTAN SINIIS TB 20 1265-10	DRISTAN		1662014. DRISTAN COLD CELCAD 365 M/S	1884055 DRISTAN COLD NO GEL CAPI T 168 M/S	1878321 DRISTAN COLD NO GELCAPI T 365 M/S	2227635 DREXOPHED TAB 120/6MG 10S OLT	2148740 SINUS TABLETS TB 24 OLT	1082031 PSEUDOEPHED HCL TB GOMG 100 URL			1493667 UNI-FED SR 40Z . URL	VG 100	24S		SC	. . .	1493675 UNI-FED TB 24 URL	Ç	폀.	2202246 CINET DECONGEST TAB TOS URL	•	1530354 CO-PTRONIL Z POLV 100 3123 LIL 1545144 PSFIIDOFPHFD HOI TR 30MG 100		1244508 PSEUDOEPHED HCL TB 60MG 100	1002856 PSEUDOEPHED HCL TB 60MG 1000	1088558 ALLERGY COLD TABS 100S CGP	2417582 PSEUDOEPHED HCL TB 60MG 100 MOR	2417590 PSEUDOEPHED HCL TB 30MG 100 MOR	1207273 EFFERVES COLD MED 20S	1204841 NASAL DECON/ANTIHIST 24S		တ	2297109 PSEUDOEPHED HCL SR 3840ML	2297125 TRIPOSED SR 240ML HLS	OM	IB 24	↲	2305/79 DEXAPHEN LA 1B 40 BOXED MJR	ASSUSSED FOR THE STATE OF THE STATE OF MAKE AND THE STATE OF THE STATE	E TAR	SSUSSUS COLD STAFFICIALS RELIEF TABS IN	2550.943 PSEUDOGEST IB SUMG 100 MJR 250.1856 SUDOGEST PLUS TR 60/4MG 24 MUR	SUDOGEST TREOMG 1000 M.		2306264 MAPAP COLD FORM TB 24 BOXED MJR
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	misc1	CGH/DEC NOVARTIS CONS	15MG/5M NOVARTIS CONS	EXPECT KNOLL LABORATORIES	COLD/CF MCNEIL CONSUMER	VDECONG MONEIL CONSTINER	CONTROL CONTROL CONTROL	OCCINC MONEIL CONSOMER	چ	60MG ROXANE			#NAME2 SKB CONSUMER HEALTHCAR	•	12.3-30 WARNER WELLCOME	DECONG WARNER WELLCOME		1.25-30 WARNER WELLCOME	SEVERE WARNER WELLCOME			2-30/5 (SCHERING-PLOUGH	٠,٠	1	PE REXALL			SCHWARZ PHARMA	SCHWAD7 BUADAAA	CMCCCL SUCMEDO	SCHWARZ PHARMA	SCHWARZ DHADAA		-	•	C) (Z. J-DUMG WEST -WARD	2.5-60MG WEST-WARD	COLDLINE	FINE COLOR SMORT			•		_	. ,	_	ر ب					·		CGH/COL: GOLDLINE			-	C	9	MERZ PHARMACELITICAL		MERC PRARMACEULICAL	MERZ PHARMACEUTICAL	INCIDIONAL DESCRIPTION	٠.	•	-	12/01	Σ		MURO	MURO	Cally	***	_	30/5 (MURO				Page 15
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	form St. misc1	<u>g</u>	LIQ 15MG/5M	SOL	SYP	9	<u>ر</u>	200	200	TAB 60MG	CANCEL	I AB COUMG	SOL #NAME?	× 100	12.5.3U	CNCCEC		SYP 1.25-30	TAB	100	FLUS SOL	SYP 2-30/5		יייייייייייייייייייייייייייייייייייייי	SYP		בות ביים	TAB SCHWARZ PHARMA	TAR COUMAD7 DUADAAA		TAB SCHWARZ PHARMA				TAB 60MG	TAR 12 FEOMIG	CALCONIC	2	1AB (2.5-50MG	CAP	TAR	200	SOL	CVD 14 25 30	05-62.1	SYP FORM-M	0	בייייייייייייייייייייייייייייייייייייי	LIQ FORM-D			SOL	SOL	CHAINE		CGH/COL	axo		TAB 30MG	CITO A C	DWING-C'Z	TAB	a V		SYP	dy		SYP 30-100/5	TSI OIT	> 12/ C10C	WIC/SUMC/SIM	1,25-30	SYP	LIO			2-30/5	SYP (2-30/5	SYP	200 400/E	SYP (30-100/5	Page 15
	form St. misc1	<u>g</u>	SAM LIQ 15MG/5M	SOL EXPECT	SYP	9	<u>ر</u>	200	200	TAB 60MG	CANCEL	I AB COUMG	SOL #NAME?	× 100	12.5.3U	CNCCEC		SYP 1.25-30	TAB	100	FLUS SOL	SYP 2-30/5		יייייייייייייייייייייייייייייייייייייי	SYP		שב יינים		TAR .	2	- A8	QAD.			TAB 60MG	TAR 12 FEOMIG	CALCONIC	2	1AB (2.5-50MG	CAP	TAR		SOL	CVD 14 25 30	05-62.1	SYP FORM-M	0	בייייייייייייייייייייייייייייייייייייי	LIQ FORM-D			SOL	SOL	CHAINE		LIQ CGH/COL	axo		TAB 30MG	CITO A C	DWING-C'Z	TAB	a V		SYP	dy		SYP 30-100/5	TSI OIT	> 12/ C10C	WIC/SUMC/SIM	1,25-30	SYP	07			SYP 2-30/5	SYP (2-30/5	SYP	200 400/E	SYP (30-100/5	Page 15
	A compared to the compared of	TRIAMINIC AM LIO	TRIAMINIC AM LIQ 15MG/5M	RU-TUSS SOL EXPECT	TYLENOL CHLD SYP	TYLENOL COUG 110	CO DEPARTMENT	LEUIACANE SOL	INFAN I YLEN DRO	PSEUDOEPHEDR TAB 60MG	סאנים מעב מעבוסטטטווסס	ישמים ארו אחבוריביטרטיבירי	NOVAHISTINE SOL #NAME?	CC # C4	יסבור בול בול ביסים	CNCCEC CIT LIA INCORNE		ACTIFED SYP 1.25-30	SUDAFED COLD TAB SEVERE		SUDAFED PLUS SOL	DRIXORAL SYP 2-30/5	LOCAL CITY OF THE LEGISLA	בות בשנו-וויינו	COUGH FORM SYP PE	CICCI CIT SMITTHON	INICIAL TIME	CODIMAL	CODIMA		CODIMAL	CODIMAI		י אייי אייי	PSEUDOEPHEDR TAB 60MG	TRIPROLIPSE TAR 12 SCHOOL	CALCO ACT TOOL TOOLOT		I KIPKULPSE I AB 2.5-50MG	GUIATUSS	PSEUDOFPHEDR TAR GOMG		GENITE SOL	TDIDDO! DOC TOOLOGICA	חפיבין דום הפיניטערואין	MULTI-SYM CD SYP FORM-M	C. CO TOTOLOGO	בייייייייייייייייייייייייייייייייייייי	DECONGEST CD LIQ FORM-D	CICCIONING		NIGHT IME SOL COLD	NIGHTTIME SOL COLD	COLLINIC		PEDIATRIC LIQ CGH/COL	GVA M MOCH HOLLON		PSEUDOEPHEDR TAB (30MG	Carre act aver Doc Condition	באוספרים ואם ויאם ויאם	ANATUSS DM TAB	ANIATIOGOLI	DO DO DANK	ANATUSS DM SYP	ANATIISS ON SYD		GUIACOUGH PE SYP 30-100/5	HAYFEBROL ILIO ISF	AVECTORING VIII	MILLED IN COMPONENT OF THE PROPERTY OF THE PRO	IKIPKOLPSE SYP 1.25-30	GUAIFED SYP	GUAIFED	CITAIRED		BROMPED SYP 2:30/5	BROMFED SYP (2-30/5	AMBENYL-D SYP	CHATTICE DE COD CON	GUIATUSS PE SYP (30-100/5	Page 15
	ndc 32 of descrip of forms misc1	43055808 TRIAMINIC AM LIQ	43055908 TRIAMINIC AM LIQ 15MG/5M	44301016 RU-TUSS SOL EXPECT	45037204 TYLENOL CHLD SYP	45038404 TYLENOL COUG LID	ASMASSIS DEDIACADE	יייייייייייייייייייייייייייייייייייייי	45050315 INFAN IYLEN DRO	54474425 PSEUDOEPHEDR TAB 60MG	באאסא פאד פרבווססרתוופסם אנאאנאא	האומים שאו אחבורום החברים המושפים המושפים	68101504 NOVAHISTINE SOL #NAME?	00 3 Ct. VID. OBLINI IN INC. T10000+5	יובטטבוי סבואנדווא טבר ברא וביט-פר	71255517 RENADRYI ALL LIO DECONG		81001982 ACIIFED SYP 1.25-30	(81080213 SUDAFED COLD TAB SEVERE		STUST SULPAPED PLUS SOL	85075701 (DRIXORAL SYP 2-30/5	THE THOUSE SECONDARY	ממחחם ביושב ביושב מחחקים ביות	122083966 ICOUGH FORM ISYP PE	CICO CIT TIME TIME	ואוסבון-וושב ורוק וכסבם	131200830 (CODIMAL TAB	131200837 CODIMAI TAB		131200843 CODIMAL TAB	131411230 CODIMAI CAP	100 Peccessor		143148501 PSEUDOEPHEDR TAB 60MG	TAR 12 FEOMIG	CALCA ACT TOOL COOLET		I KIPKOUPSE IAB 2.5-50MG	CAP	182137410 PSFUDOFPHEDR TAR GOMG		SOL	CVD 14 25 30	חפיבין דום הפיניטערואין	SYP FORM-M	0	בייייייייייייייייייייייייייייייייייייי	DECONGEST CD LIQ FORM-D			NIGHT IME SOL COLD	SOL	CHAINE		LIQ CGH/COL	axo		TAB 30MG	CANO A C. GAT! DOO! COCIOT!	באוספרים ואם ויאם ויאם	TAB	ANATIOCONIA TAB	DO DO DANK	SYP	dy		GUIACOUGH PE SYP 30-100/5	TSI OIT	AVECTORING VIII	MILLED IN COMPONENT OF THE PROPERTY OF THE PRO	IKIPKOLPSE SYP 1.25-30	SYP	07	CITAIRED		BROMPED SYP 2:30/5	SYP (2-30/5	SYP	CHATTICE DE COD CON	GUIATUSS PE SYP (30-100/5	Page 15
	ndc 32 of descrip of forms misc1	43055808 TRIAMINIC AM LIQ	43055908 TRIAMINIC AM LIQ 15MG/5M	44301016 RU-TUSS SOL EXPECT	TYLENOL CHLD SYP	TYLENOL COUG 110	ASMASSIS DEDIACADE	יייייייייייייייייייייייייייייייייייייי	INFAN I YLEN DRO	PSEUDOEPHEDR TAB 60MG	סאנים מעב מעבוסטטטווסס	האומים שאו אחבורום החברים המושפים המושפים	NOVAHISTINE SOL #NAME?	CC 3 C4 VID COUNTY INTO TACOUCHE	יובטטבוי סבואנדווא טבר ברא וביט-פר	CNCCEC CIT LIA INCORNE		81001982 ACTIFED SYP 1.25-30	SUDAFED COLD TAB SEVERE		STUST SULPAPED PLUS SOL	DRIXORAL SYP 2-30/5	THE THOUSE	ממחחם ביושב ביושב מחחקים ביות	COUGH FORM SYP PE	CICO CIT TIME TIME	ואוסבון-וושב ורוק וכסבם	CODIMAL	CODIMA		131200843 CODIMAL TAB	CODIMAI	100 Peccessor		143148501 PSEUDOEPHEDR TAB 60MG	TRIPROLIPSE TAR 12 SCHOOL	CANA TOO TOO TOO TOO TANK	4 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	143190025 ITRIPROUPSE IAB (2.5-50MG	GUIATUSS	PSEUDOFPHEDR TAR GOMG		GENITE SOL	TDIDDO! DOC TOOLOGICA	ומיים ביים ביים ביים ביים ביים ביים ביים	182603237 MULTI-SYM CD SYP FORM-M	C. CO TOTOLOGO	יייייייייייייייייייייייייייייייייייייי	182603344 DECONGEST CD LIQ FORM-D	CICCIONING	Leaf Land Control of C	18ZBUBB38 NIGHTTIME SOL COLD	NIGHTTIME SOL COLD	COLLINIC		182615537 PEDIATRIC LIQ CGH/COL	GVA M MOCH HOLLON		IPSEUDOEPHEDR TAB (30MG	CANO A C. DATE DOM CODICT: 001278CS1	שוספריכים שבורות ביים היים היים היים היים היים היים היים	ANATUSS DM TAB	SEGNOSCOS ANIATHOCOMA TAD	WO COOLAND	ANATUSS DM SYP	ANATIISS ON SYD		S04Z48U// GUIACOUGH PE SYP 30-100/5	HAYFEBROL ILIO ISF	A 25 8 50 0 A 17 CLOSING CO. V. C.	שוניים ביים ביים ביים ביים ביים ביים ביים	420800004 IKIPKOLPSE SYP 1.25-30	GUAIFED SYP	GUAIFED	CITAIRED		451420104 BROMFED SYP (2:30/5	BROMFED SYP (2-30/5	AMBENYL-D SYP	479003804 CHATHEE DE COS 130 400/E	4/2003894 GUIALUSS PE SYP 30-100/5	Page 15

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建建筑学等区 度	2164424 SINUS RELIEF TB 100	2163962 DEXAPHEN SA TB 120/6 10 2163920 DEXAPHEN SA TB 120/6 20	2163731 ATT NITE COLD SR 120MI	2163665 SIMPLET TB 100	2163947 COLD SYMPTOMS RELIEF TB 50	2164358 PS EUDO-GEST SR 40Z	2163681 PSEUDOGEST TB 30MG 24	1402882 KOLEPHRIN DM CL 30	1402841 KOLEPHRIN CL 36	1632488 NASABID 100S SEE#2514628	2695161 Tylenol Flu Night PC6	2695021 Tylenol Flu Night 10	2695039 Tylenol Flu Night GC 20	2070001 Tripol P-Ephed SR Fruit	2070902 Medi-Tuss DAC SR STR Ins 16 oz	184 1261 UN and Antinasi 100	506021 UN and Antinas TB 24	843036 UN night Colds Med EI 10	854009 Cophene-S SR 480 ml	2017572 Respinol-G 400/60 100	2665800 HayFEBROL SF SL 30 ml	8 HayFEBROL S	2665826 Hayfebrol SF SL 480 ml	2695195 Decohistine10 mg 120 ml	2621316 Carbodec DM SR 3840 ML	2021324 Carbodec UM SK 120 m	1084547 Zentrey I A TR 600 mg 450 m	2701878 Cardec DM TTT 15 mi	2701902 Cardec DM TTT 120 ml	2704070 Desihist TB 120/6 100	2704054 Desihist TB 120/6 1000	2699940 Gulatuss DAC TTT 10 mg 120	2699908 Gulatuss DAC TTT SR 10 MG 48	2697431 Dinistine TTT EX 120 ML	2097415 Dinisune 111 SK 10 mg	2704467 Beardooks 4/0:05 TTT 600 mm	269718 Hajotussin DAC 10 mg 120 mg	2699676 Halotussin DAC TTT SR 10 mg 480 ml	2701597 Pseudoephed Guaf/TTT CD 300 mg 100	2701209 Pseudoephed Guaf/TTT 250 mg 100	2703320 Nasal Decong TTT 120-12 100	2703361 Nasat Decong PED 60-6 mg 100	2694776 U/L Pseudo Gest 30 mg 24	2894206 U/L Aprodine 24	2629160 Novagest EX 3840 ml	2694768 U/L Pseudo Gest TB 24	U/L All-nite Cold	2694180 U/L All-nite Cold Cherry 180 ml	U/L Cold Symptom 50	20096111 apties DM SR 480 m	2695748 Pseudoenhedrine th 30 mg 100	2696755 Pseudo Gtabs TB 60 mg 100	1981182 Clorled 10 mg 480 ml	2621100 Lemohist Plus 1000
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misc1 Section Misch Misc	GIMAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS MAJOR PHARMACEUTICALS		MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS		MAJOR PHARMACEUTICALS	PFEIFFER	PFEIFFER	90-250CR ABANA PHARMACEUTICALS						AMERICAN PHARMACEUTICAL			DUNHALL	MISEMER	SCOT-TUSSIN	SCOT-TUSSIN	SCOT-TUSSIN	MORION GROVE PHARMACEUTICALS	KUGBI	Nacion Nacion	SANOFIPHARMACEUTICALS	HLMOORE	H L MOORE	. ب	HLMOORE	.		H L MOOKE	H MOORE	HIMOORE	_	Ŧ	HLMOORE	I	I	H L MOORE			MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	MAJOR PHARMACEUTICALS	COLUMBIA DRIFE	COLUMBIA DRUG	MASON DISTRIBUTORS	MASON DISTRIBUTORS	STEWART JACKSON	SENECA
17.1	MC25-05	6-120	COLD/CG		COLD	30MG/5M	30MG		····	90-250CF	NICHTIM	NICHTIM	WILHOIN:	-	#NAME?	DECONG	DECONG	CD FORM	- <i>.</i>			, S	SF	EXPECT		:	120-600			6-120	6-120			CYBECT	באובר	120-600	DACSF	DAC SF	60-300SR;	120-250	12-120CR	6	SOMG	2.5-60MG	EXPECT	PLUS	FORMUL	TOKANOL CO.C.	3		30MG	60MG		FLUS
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DEA COMPLIANCE MANUAL

APPENDIX F

DEA Correspondence



U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

JUN 2 5 1992

Ms. Sherry Haber National Wholesale Druggist Association 105 Oronoco Street Alexandria, Virginia 22314

Dear Ms. Haber:

It has been brought to the attention of the Drug Enforcement Administration (DEA) that some confusion exists regarding the proper completion of the DEA Form 222 with respect to the "number of lines completed." This letter is written to help alleviate some of the confusion.

Title 21 of the Code of Federal Regulations (CFR), section 1305.06(b) states that only one item shall be entered on each numbered line. It further states that the total number of items ordered shall be noted on the order form in the space provided. On the current version of the DEA Form 222, the aforementioned "space provided" is termed "number of lines completed." When the above requirements are followed to the letter, there is no discrepancy between the number of items ordered and the number of lines completed.

Problems in interpretation have been encountered when the purchaser either uses more than one line to describe an item or voids an item. In the first instance, the correct interpretation would be to list the number of items ordered on the form in the space labeled "number of lines completed." The DEA Form 222 will be revised in its next printing to rename the heading "number of items ordered."

The issue of voided lines on the order form is perhaps a bit less clear cut in its interpretation. In strictly interpreting the regulations, the only conclusion which can be reached which is not open for interpretation is that a supplier may not fill an order form which "shows any alteration, erasure, or change of any description" (21 CFR 1305.11(2)). In fact, instructions provided on the reverse side of the DEA Form 222 advise the purchaser

Ms. Sherry Haber Page Two

not to make erasures or alterations. They state that if an error should be made, all copies of the form should be voided and kept on file.

In addition, the regulations imply that only a supplier, not a purchaser, may void an item on a DEA Form 222. Section 1305.15(a) of the regulations states:

A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

Consequently, the supplier is the only individual that has the authority to indicate the cancellation on the order form.

A separate but related issue has also been raised regarding generic substitution of order forms. DEA policy does not preclude generic substitution of identical products provided that the name and National Drug Code number of the actual product shipped is reflected on the form. Therefore, it would be acceptable to make a substitution provided that the customer agrees to accept a generic rather than a brand name product, the generic product of a manufacturer other than the one specified or a brand name product rather than a generic one. Therefore, the purchaser will not be required to submit a new DEA Form 222 to accommodate such a change.

Please disseminate the enclosed information to the members of your organization in an effort to dispel any problems they are perhaps encountering with the form. Thank you for your attention to this matter.

Sincerely

Gene R. Haislip

Deputy Assistant Administrator
Office of Diversion Control



TO: Clarence Crisp/Cdc

Paul Exlev/Ovc

Ron Franks/Bos Rick Gliot/Cdc

Ben Jones/Zan

Geoff Kirkham/Har -- Carol Verrastro/Buf Pete Westermann/Syr

> CC: George Bennett

DATE: June 29, 1992

FROM:

SI IRI.

Steve Reardon/Bos Steve

Order Forms (DEA Form 222)

At a recent NWDA/DEA meeting that I attended, DEA issued the attached letter to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed, voided or canceled lines, and generic substitutions. The regulatory interpretations are as follows:

- When two lines are used on an order form to describe one item, the number of lines completed at the bottom should be one. If two lines are used to order one item and "two" is entered in the number of lines completed, the order form must not be filled.
- A customer cannot void or cancel a line on the order form. If an order form is received from a customer with a voided or canceled line, the order form is considered defective and cannot be filled. Only a supplier may void an item on DEA Form 222. The customer may cancel a line by notifying the supplier in writing.
- It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution.

Please read the letter for the specifics of these interpretations and pass the information on to the appropriate personnel in your division. Your customers should be notified regarding the consequences of their voiding or canceling a line.

DEA has informed their local offices of these interpretations, and you can expect regulatory enforcement to be consistent with the information contained in the letter.

If you have any questions, please call.

Attachment



Clarence Crisp/Cdc

Paul Exley/Ovc

Ron Franks/Bos Rick Gliot/Cdc

Ben Jones/Zan

Geoff Kirkham/Har
- Carol Verrastro/Buf
Pete Westermann/Syr

CC: George Bennett

DATE: T.

June 29, 1992

FROM:

Steve Reardon/Bos Steve

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 defective and cannot be filled. Only a supplier may void an item on DEA Form 222.
 The customer may cancel a line by notifying the supplier in writing.
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Please read the letter for the specifics of these interpretations and pass the information on to the appropriate personnel in your division. Your customers should be notified regarding the consequences of their voiding or canceling a line.

DEA has informed their local offices of these interpretations, and you can expect regulatory enforcement to be consistent with the information contained in the letter.

If you have any questions, please call.

Attachment

0:

John Dewees

Paul Exicy

Ron Franks

Rick Gliot

Ben Jones

Willard Lawrence

Doug Pace

Carol Verrastro

Pete Westermann

CC:

George Bennett Clarence Crisp December 16, 1992

FROM:

Steve Reardon

SLEL:

DEA Form 222

Please be advised that DEA has made changes on DEA Form 222 (sample attached). They are as follows:

- "No. of Lines Completed" has been changed to "No. of Items Ordered (Must Be Ten or Less)"
- Instruction #8 on the reverse side was changed from:
 - Enter the number of items ordered this should correspond to the number of lines used. If this number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it.

to:

8. Enter the number of different items ordered — this generally should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it.

These changes were made in an attempt to facilitate compliance with 21 CFR 1305.06(b) which reads:

(b) Only one item shall be entered on each numbered line. There are ten lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for carfentanil etorphine diprenorphine shall contain only these substances. The total number of items ordered shall be noted on that form in the space provided.

Please pass this information on to the appropriate personnel in your division. If you have any questions, please call.

Attachment



U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20337

APR 0 = 1993

Mr. Dan White
Director, Distribution Projects
and Regulatory Affairs
McKesson Drug Company
One Post Street
San Francisco, California 94104-5296

Dear Mr. White:

Reference is made to your recent letter in which you asked for clarification of the Drug Enforcement Administration's (DEA) policy regarding the "Number of Items Ordered" box on DEA Forms 222.

We had hoped to eliminate much of the confusion regarding the proper completion of order forms by changing the heading for this box from "Number of Lines Completed" to "Number of Items Ordered," but based upon your inquiry and others we have received, it is apparent that some confusion still exists.

In your letter, you cited as an example an instance where a purchaser has used five lines on a DEA form 222 to order controlled substances. Line #1 and line #4 both contain entries for the same product and package size, i.e. *1 x 100 Ritalin Tab 5mg." You asked whether the "Mumber of Items Ordered" would be "five" or "four."

Section 1305.06 (c) of Title 21 of the Code of Federal Regulations (CFR) specifies that "An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance." It is our position, therefore, that in the example you cited, four items were ordered. If the purchaser in this case had erroneously indicated that five items had been ordered (most likely based on the fact that five lines had been completed), we would deem this to be a minor error which could be corrected.

Mr. Dan White Page Two

It has always been our intent to keep all of our Diversion Investigators knowledgeable about interpretations of the Controlled Substances Act and implementing regulations as well as DEA policy. If you are awars of any inconsistencies in our field offices' interpretation of the CSA, the regulations or DEA policy, please bring it to Ms. Carter's or my attention so the situation can be rectified.

If I can be of further assistance, please let me know.

Sincerely,

G. Priores Girchel, Chief Liaison and Policy Section Office of Diversion Control



U.S. Department of Justice

Drug Enforcement Administration

... Washington, D.C. 20537

MAY 1 8 1993

Ms. Diane P. Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

This is in response to your letter of March 8, 1993, regarding the issues raised at the National Wholesale Druggists' Association's (NWDA) Regulatory Affairs Working Group meeting in San Antonio.

The issues raised at the meeting are important and we look forward to continuing to work with the NWDA on matters concerning compliance with Federal and state laws and regulations governing controlled substances. We have relayed the working group's concerns regarding consistency in the Drug Enforcement Administration's interpretation of policy to all of our field offices. We have also reminded them that responses to policy questions should be made in writing if requested by the registrant.

Thank you for allowing members of the Office of Diversion Control staff to meet with you. We believe that by sharing concerns and ideas to prevent the diversion of legitimate controlled substance, both DEA's mission and NWDA's needs will be met.

Sincerely

G Thomas Gitchel, Chief Limison and Policy Section Office of Diversion Control

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U.S. Department of Justice

Drug Enforcement Administration



JUN 23 1993

Mr. Larry L. Holland Corporate Director Security and Regulatory Compliance Alco Health Services Corporation P.O. Box 959 Valley Forge, Pennsylvania 19482

Dear Mr. Holland:

This is in response to your letter of April 22, 1993, in which you question the use of a former owner's Drug Enforcement Administration (DEA) registration by the new owner following the purchase of a pharmacy. There have been certain instances recently which have resulted in our reevaluating the circumstances under which these procedures may be used.

It is DEA's policy that upon purchasing a pharmacy the new owner must obtain a new DEA registration prior to dispensing controlled substances. However, we recognize that there may be occasions when, due to circumstances beyond the new owner's control, issuance of the appropriate state permits and, consequently, the new DEA registration may be delayed. In such situations, it may be permissible for the new owner to continue the business of the pharmacy under the previous owner's registration, provided certain conditions are met by both new and old owners.

The primary condition is that both the buyer and seller enter into a power of attorney that specifically sets forth the following:

- 1. The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- 2. The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;

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- 3. The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- 4. The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

In addition, the buyer must notify the appropriate local DEA office of the proposed use of the seller's DEA registration and, if requested, furnish a copy of the agreement. Should circumstances warrant, the local DEA office may withhold permission for the buyer to use the seller's registration number. The buyer cannot automatically assume that they will be authorized to utilize the seller's registration to conduct controlled substance activities.

With respect to your concerns regarding good faith verifications under such conditions, the best approach is to require that a copy of the power of attorney be provided with the copy of the registration certificate.

I trust the above adequately addresses your concerns. If you have any further questions or comments, please do not hesitate to contact this office at (202) 307-7297.

Sincerely.

G. Thomas Gitchel, Chief Liaison and Policy Section Office of Diversion Control

Cardinal Health

TO

Tom Blaylock/National Specialty Serv. DATE:

John Dewees/Marmoc

Paul Exley/Ohio Valley

Ron Franks/Daly

Rick Gliot/Chapman

Ben Jones/Bailey

Brian Landry/Mississippi

-Doug Pace/Florida

John Roth/Solomons

Carol Verrastro/Ellicott

Pete Westermann/Syracuse

CC:

George Bennett/Dublin

June 29, 1993

Steve Reardon/Daly

DEA Policy

FROM

SLIBI

Typically, local DEA offices are willing to provide registrants with regulatory policy interpretations but are hesitant to put these interpretations in writing. However, according to the attached letter, the field offices have recently been instructed to respond to policy questions in writing if requested by the registrant. In response to this new directive from Washington, our policy should be to ask for all interpretations of DEA regulations and policies or approvals of procedures for your operation to be put in writing. This practice will protect us against potential violations that could result when being inspected by DEA investigators who disagree with the interpretation or are new to the local office. If the local office is hesitant to put something in writing, please feel free to provide them with a copy of this letter or contact me, and I will handle it.

If you have any questions, please call.

Attachment

Cardinal Health

Sales and Operations Personnel Linda Zarlengo

DATE. TROM: August 25, 1993

CC: George Bennett Pete Westermann SUBI

Steve Reardon June

Change of Pharmacy Ownership: **DEA Policy**

Change of pharmacy ownership and continuing operation on a previous owner's DEA registration is an issue which has created ongoing confusion and inconvenience for us and our customers because of varying local DEA interpretations as to whether or not this is allowed.

DEA Headquarters recently documented DEA's official policy in the attached letter, which states that continued operation is permissible when certain conditions are met by both the current and previous owners.

The primary condition is that both the buyer and seller enter into a power of attorney that specifically sets forth the following:

- 1. The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- 2. The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller,
- 3. The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- 4. The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling to the new owner, you should obtain a copy of the power of attorney and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy.

If you have any questions, please call.

Attachment



10

Sales and Operations Personnel

DATE

August 25, 1993

CC:

George Bennett

FROM:

Steve Reardon fund

Mid-Level Practitioners (MLPs)

The Drug Enforcement Administration (DEA) published a final rule in the June 4 Federal Register establishing a new category of DEA registrants, mid-level practitioners (MLPs). The rule defines MLP as "an individual practitioner... other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." Examples of MLPs include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

MLPs will now be registered with DEA, but their authority to prescribe, dispense, and order controlled substances is granted by the state in which they practice and varies greatly among the states and types of MLPs (see attached). The final rule places responsibility for verifying this authority on the supplier, a complicated task at best.

I don't believe MLPs represent a significant new class of customers who would generate large volume sales and, because of the compliance difficulties posed by the authority verification responsibility, recommend that we do not sell directly to them. However, if this turns out not to be the case, we can reevaluate this position.

Please pass this information along to the appropriate staff in your division. If you have any questions, please call.

NOTE:

The new MLP registration number will begin with the letter "M" rather than the letters "A" or "B" currently used for traditional practitioners.

Attachment

Distribution:

Denzel Bibey
Dave Blaylock
Tom Blaylock
Jim Bonanni
Terry Brown
Chip Caney
John Dewees

Paul Exley
Rick Gliot
Pat Jensen
Lindsley Keeton
John Kilgour
Les Killebrew
Brian Landry

Bernie Livingston Gene Morrow Patrick O'Connor Doug Pace Alan Phair Sherry Rahn John Roth Roy Stromski Jeff Tuller Mike Vaughan Carol Verrastro Pete Westermann



Dwight A. Steffensen, Charman of the Board Ronald J. Streck, President & CEO

National Wholesale Druggists' Association

P.O. Box 2219, Reston, VA 22090-0219. Fax # 703/787-6930.
1821. Michael Faraday Drive, Suite 400, Reston, VA 22090-5346 • 703/787-0000.

August 20, 1993

TO:

Active Member CEO's

Government Affairs Committee Regulatory Affairs Working Group

FROM:

Diane Goyette

Director of Regulatory Affairs

Robin Pollini Regulatory Analyst

SUBJECT: DEA Mid-level Practitioner Rule: Information on State Prescribing Authority

As previously reported to you, the Drug Enforcement Administration (DEA) published a final rule in the June 4 Federal Register establishing a new category of DEA registrants. Under this rule, mid-level practitioners (MLPs), such as physician assistants and nurse practitioners, will obtain and use their own DEA numbers to prescribe, dispense and order controlled substances, subject to state requirements. The rule went into effect on July 1, 1993. We have attached a copy of a June 1993, Government Update article outlining the new regulations (Attachment A).

MLPs will now be registered with DEA, but their authority to dispense controlled substances is granted by the state in which they practice. The final rule places the responsibility for verifying the degree of the MLP's authority to order and prescribe controlled substances on pharmacists, wholesalers and other parties in the distribution chain. Because prescribing authority varies so widely among states and types of MLPs, wholesalers need to be familiar with the restrictions imposed by each state that they service.

NWDA has developed the enclosed materials to familiarize you with the MLP prescribing authority in each state. We hope you will find them helpful in determining your obligations under the new DEA rule. The materials are based on information received from the National Association of Boards of Pharmacy, the American Academy of Physician Assistants, the American Nurses Association and various state authorities. In addition to the Government Update article, we have included the following:

Mid-Level Practitioner Prescribing Authority by State Chart (Attachment B) - This chart provides information on the prescribing authority, per state, for the following MLPs: doctors of homeopathy, physician assistants, advanced registered nurse practitioners, "other nurses" and optometrists. This is only a <u>partial</u> list, containing information on the

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more commonly encountered MLPs. It should be noted that other practitioners may be covered under the MLP rule. For the purposes of this chart, the term "other nurses" includes clinical nurse specialists, nurse midwives, certified registered nurse anesthetists and various nurse practitioner specialists.

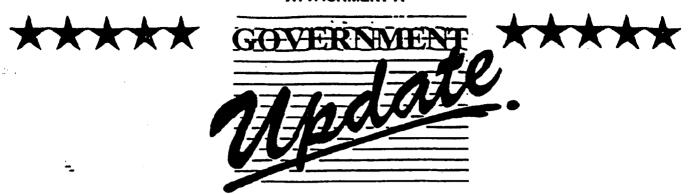
The chart takes each state and assigns the five MLP groups a number representing their prescribing authority under that state's regulations. MLPs with independent prescribing authority (category 1) or limited prescribing authority (category 3) are probably of the most concern to you as a wholesaler because these MLPs have the greatest degree of authority to prescribe. Dependent describing authority (category 2) in some states may also be of concern. A description of the categories appears at the beginning of the chart.

Notes on Dependent and Limited Mid-Level Practitioner Prescribing Authority, by State (Attachment C) - These notes accompany the chart to provide additional information on dependent and limited prescribing authority for physician assistants and nurses. Accordingly, each category 2 and 3 listing on the chart has a corresponding explanation in the notes. Many of the chart entries for other nurses "vary." Where this variation could not be covered in the notes, you will need to contact the state for more information.

State Contact Listings (Attachment D) - Because there are so many different types of MLPs and the prescribing authority for each of these MLPs varies widely by state, you may need to supplement the enclosed information by contacting the states for more information. The contacts at the state Boards of Pharmacy and state licensing agencies listed in this package should be able to answer any questions that you have regarding MLP prescribing authority.

We hope that the enclosed materials will assist you in responding to the requirements of the new DEA mid-level practitioner rule. As new information becomes available we will update these materials for your use. If you have questions regarding the enclosed materials or the mid-level practioner rule, please contact Robin Pollini, NWDA Regulatory Analyst, Ext. 242.





National Wholesale Druggists' Association

PO Box 2219. Reston, VA 22090 - 703/787-0000

Vol. 13 No. 6

June 1993

DEA Now Registers MLPs

Changes Could Pose New Burdens For Pharmacists, Wholesalers

The Drug Enforcement Administration (DEA)

published a final rule in the June 4 Federal Register establishing a new category of DEA registrants.

Under the new rule, which goes into effect on July 1, 1993, mid-level practitioners (MLPs) will obtain and use their own DEA numbers in dispensing controlled substances, subject to restrictions imposed by their state of practice.

The final rule defines an MLP as "an individual practitioner...other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." DEA considers "dispensing" to include administering, prescribing and directly dispensing—delivering to the ultimate user — controlled substances. Examples of MLPs include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants.

Until now, MLPs have used the DEA number of their supervising practitioner or institution, again subject to state requirements. The new MLP registration numbers will begin with the letter "M" rather 'an the letters "A" or "B," currently used for tradiconal practitioners, so they can be identified as a separate registration category.

Although MLPs now will be registered with DEA, their authority to dispense controlled substances is granted by the state in which they practice and varies widely. In the final rule, DEA acknowledges that verifying MLP dispensing authority will pose difficulties, but notes that it will be the responsibility of pharmacists, wholesalers and other parties in the distribution chain to contact the appropriate state officials to verify the degree of dispensing authority an MLP has been granted.

The burden of this verification is expected to fall primarily on pharmacists, who most commonly will receive orders for controlled substances in the form of individual prescriptions from MLP prescribers. However, drug wholesalers also can expect to handle orders for controlled substances bearing the M-designated DEA number. The unique number format should alert wholesalers to the fact that an MLP customer may or may not be authorized to order controlled substances in a given state. Since this authority varies so widely, wholesalers need to be familiar with the restrictions imposed by each state it services.

NWDA currently is compiling information on the states' laws governing MLPs, and will distribute this information to members as soon as it is complete.

ATTACHMENT B

MID-LEVEL PRACTITIONER (MLP) PRESCRIBING AUTHORITY BY STATE

This table provides information on state prescribing authority for a limited number of mid-level practitioners (MLPs). Please note that for the purposes of this chart, the term "other nurses" includes clinical nurse specialists, nurse practitioners and various nurse practitioner specialists. The codes used to describe the authority granted in each state are as follows: 1 - Independent prescribing authority: The MLP has independent authority to order or prescribe controlled and non-controlled substances.

2 - Dependent prescribing authority: The MLP may order or prescribe certain controlled substances under the supervision of a physician. See the notes that accompany this table for specific requirements by state.

3 - Limited prescribing authority: The MLP's prescribing authority is limited to certain types of drugs. See the notes that accompany this table for specific restrictions by state.

vary" - Prescribing authority varies among different types of nurses. Contact the state for more information. The MLP may not order or prescribe controlled and non-controlled substances.

STATE	ростов оғ номеоратну	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Alabama	4	4	4	4	4
Alaska	4	2	-	2	4
Arizona		2	1,2	4	-
Arkansas	_	4	4	4	
California	4	4	3	vary	4
Colorado	4	2	2	vary	4
Connecticut	4	4	2	vary	4

STATE	DOCTOR OF	PHYSICIAN ASST	ADVANCED	OTHER	OPTOMETRISTS
			NURSE PRACTITIONERS		
Delaware	4	4	4	4	4
District of Columbia	+	2	2	2	-
Florida	7	4 (see notes)	2	4	-
Georgia	4	4	4 (see notes)	4	-
Hawaii	4	*	*	4	4
Idaho	*	2	-	vary	-
Illinois	4	4	4	4	4
Indiana	4	4	4	4.	-
lowa	4	2	3	4	-
Kansas	4	2	2	4	-
Kentucky	4	4	4	4	3,4
Louislana	4	4	4	4	4
Maine	*	2	2	vary	4
Maryland	4	4	2	vary	4
Massachusetts	4	2	4	vary	4
Michigan	7	2	2	23	4
Minnesota	4	2	2	vary	4
Wissksippi	4	4	2	veiy	4
Missour	4	2	4	4	-

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	other Nurses	OPTOMETRISTS
Montana	4	3	1	vary	1
Nebraska	4	2	2	2	-
Nevada	1	2	2	4	4
New Hampshire	4	2	1	vary	4
New Jersey	4	4	4	vary	3
New Mexico	4	2	2	vary	
New York	4	2	1	vary	4
North Carolina	4	2	2	vary	1
North Dakota	7	2	2	2	-
Ofilo	4	4	4	vary	1
Oktahoma .	4	4	4	4.	3
Oregon	4	2	1	vary	
Pennsylvania	4	4	4	4	4
Puerto Rico	4	4	4	4	4
Rhode Island	4	2	3	vary	1,4
South Carolina	4	2 (see notes)	2	vary	4
South Dakota	4	2	2	4	-
Tennessee	4	4	2	vary	_
Texas '	4	2	2	vary	

4. 1.5 · .

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Utah	4	2	2	vary	2
Vermont	4	2	1	vary	4
Virginia	4	4 (see notes)	2	vary	1,4
Washington	4	2	1	1	4
West Virginia	4	2	3	4	4
Wisconsin	4	2	4	4	4
Муотіпд	4	2	1,2 (see notes)	4	*

ATTACHMENT C NOTES ON DEPENDENT AND LIMITED PRESCRIBING AUTHORITY BY STATE

AK - Physician Assistants: PAs may prescribe Schedules III-V controlled substances.

Nurses: Advanced registered nurse practitioners (ARNPs) have independent prescribing authority. The Board of Nurses may limit the types of drugs that they can prescribe in accordance with their education and experience.

AZ - Physician Assistants: PAs may prescribe Schedules II-III in a limited 48-hour supply, and Schedules IV-V in a 34-day supply. All prescriptions must contain the name of the supervising physician.

Nurses: Nurse practitioners (NPs) have full prescriptive and dispensing authority upon application and fulfillment of criteria established by the Board of Nursing. NPs may prescribe Schedule II and III drugs (limited to a 48-hour supply per patient) and Schedule IV and V (a one-month supply with no refills per patient). Other drugs may be refilled five times or up to one year.

- CA Nurses: NPs who have satisfactorily completed at least six months of MD-supervised experience in furnishing drugs or devices, who have satisfactorily completed a course in pharmacology and who have been issued a furnishing number by the Board of Nursing may furnish certain drugs or devices incidental to the provision of family planning services.
- CO Physician Assistants: Physicians may delegate limited prescribing authority to certified PAs. PAs may issue prescriptions for non-controlled substances only.

Nurses: NPs may write prescriptions for select drugs pursuant to an established protocol.

- CT Nurses: Nurse practitioners, clinical specialists, nurse midwives and nurse anesthetists may apply for prescriptive practice privileges. ARNPs must apply for licensure in order to prescribe. Dispensing privileges are also granted to ARNPs functioning in public clinics.
- DC Physician Assistants: PAs may sign prescriptions for non-controlled substances on Rx pads that contain the name of the supervising physician and PA.

Nurses: DC provides dependent prescriptive authority for NPs, nurse midwives and nurse anesthetists for Class II-V drugs according to existing federal laws.

FL - Physician Assistants: Legislation passed in 1992 grants PAs dependent authority to prescribe drugs according to a formulary. Although the legislation has been passed, the mechanisms for implementing the legislation will not be fully in place until early fall.

Nurses: NPs have dependent prescriptive privileges for non-controlled substances.

GA - Nurses: Although nurses have no prescribing authority, a 1989 law states that through a protocol a physician may delegate to a nurse in advanced practice the authority to order controlled substances and dangerous drugs.

ID - Physician Assistants: PAs may write prescriptions as agents of their supervising physicians by applying to the board for prescription-writing authority. The board-approved formulary is limited to 24 categories of legend drugs (antibiotics, non-narcotic analgesics, contraceptives, topical and local anesthetics, etc.).

Nurses: Prescribing is allowable for approved NPs based upon a formulary in the rules; NPs may not prescribe controlled substances.

Physician Assistants: Physicians may delegate the function of prescribing drugs, controlled substances, and medical devices to a licensed PA. PAs may prescribe Schedules II-V controlled substances, except Schedule II stimulants and other depressants. PAs may order Schedule II stimulants and depressants with the prior approval and direction of a physician, and may request, receive and supply sample drugs and medical devices.

Nurses: Nurses may write prescriptions for non-controlled substances under an established protocol.

KS - Physician Assistants: PAs may issue prescription orders orally by telephone for Schedule II controlled substances in an emergency. The supervising physician must provide a written prescription within 72 hours. PAs may orally by telephone transmit prescription orders for Schedules III, IV and V controlled substances, as well as non-controlled substances, which may also be prescribed in writing.

Nurses: NPs may prescribe under jointly adopted protocols between the nurse and physician.

ME - Physician Assistants: Physicians may authorize PAs to prescribe or dispense controlled substances. Authorized PAs may issue prescriptions for categories of drugs on the board-approved formulary, which excludes Schedule II controlled substances. All parenterals except insulin are excluded unless prescribed for administration within a hospital, clinic, physician's office or nursing home. The amount of scheduled drugs that may be prescribed may be no more than 100 dose units or a 90-day supply, whichever is less.

Nurses: Prescriptive authority is approved by the Board of Medicine. Limits in prescribing formulary by exclusion (i.e., narcotics).

- MD Nurses: NPs prescribe medications as agreed upon in writing with physicians.
- MA Physician Assistants: PAs may write prescriptions for legend drugs and controlled substances (Schedules II-V). Prescriptions and medication orders must be issued in accordance with guidelines developed by each PA and supervising physician.
- MI Physician Assistants: Physicians may delegate to PAs the prescription of drugs other than controlled substances. The supervising physician's name must be indicated in connection with each individual prescription.

Nurses: Physicians may delegate the prescribing of drugs to RNs, excluding controlled substances.

MN - Physician Assistants: Physicians may delegate to PAs the authority to prescribe and administer legend drugs and medical devices that are appropriate to the practice. This delegation must be approved by the board. Physician and PA must have an internal protocol that lists the drugs and medical devices the PA may prescribe or administer.

Nurses: NPs have prescriptive authority when delegated to do so under a written agreement with a physician. Nurse midwives also have authority to prescribe.

- MS Nurses: NPs have statutory prescriptive authority granted by the Board of Nursing. This authority is based on the accepted protocol, which lists the treatments and medications the NP expects to prescribe in his or her practice. NPs are not allowed to prescribe controlled substances.
- MO Physician Assistants: The regulations do not impose restrictions on the types of drugs that PAs can prescribe. This is left to the discretion of the supervising physician.
- MT Physician Assistants: PAs may prescribe, dispense and administer drugs to the extent authorized by the rules of the medical board and/or the physician's utilization plan. Authority granted to the PA may include Schedule III, IV and V controlled substances, and Schedule II with a 48-hour limit. The medical board does not permit PAs to prescribe thrombolytics.
- NE Physician Assistants: PAs can only prescribe medications as an agent of a supervising physician. The PA may prescribe medications in the name of the supervising physician if the authority has been assigned by the physician (Schedule II controlled substances used for pain control are limited to a 72-hour supply). Prescription label must bear the name of both the PA and the supervising provision.

Nurses: ARNPs have dependent authority based on a practice agreement with their supervising physician.

NV - Physician Assistants: PAs may prescribe poisons, dangerous drugs or devices, but not controlled substances. PAs must be registered with the Board of Pharmacy.

Nurses: ARNPs may prescribe if certified by the Board of Nursing.

- NH Physician Assistants: Prescriptions transmitted by PAs must be based on patient-specific orders from the supervising physician or on written protocols. All Rx for controlled substances must contain the supervising physician's DEA number with the PA's state license number as a three-digit suffix.
- NM Physician Assistants: PAs may prescribe, administer and distribute dangerous drugs other than controlled substances provided it is done under physician supervision and within medical board-approved guidelines and formulary. The formulary lists 70 types of drugs PAs may prescribe.

Nurses: NPs have prescriptive privileges with their own signature in accordance to written protocols with physician supervision.

- NY Physician Assistants: Physicians may assign prescribing authority to registered PAs. PAs may not prescribe controlled substances.
- Physician Assistants: PAs are authorized by law to write prescriptions under conditions specified by the state board of medical examiners. PAs may prescribe drugs from a medical board-approved formulary that excludes controlled substances and parenteral preparations except insulin, immunizations, serum, epinephrine and benadryt. A prescription may not indicate a refill except birth control pills and may be for no more than 100 dosage units or a one-month supply.

Nurses: ARNPs may prescribe non-controlled substances under the supervision of a physician.

ND - Physician Assistants: PAs may prescribe controlled substances, except Schedule II, as agents of their supervising physicians.

Nurses: The Board of Nursing is responsible for delegating prescribing authorities. Once approved by the Board, nurses may prescribe drugs under the supervision of a physician. The types of drugs that a nurse can prescribe are determined by their area of expertise (six practice areas) designated by the Board.

- OR Physician Assistants: Physicians may delegate to PAs the authority to administer and dispense limited emergency medications and to prescribe. The medical board's Physician Assistants Committee is authorized to review applications for prescribing and dispensing privileges and to recommend a formulary that may include all or part of Schedules III through V. To prescribe Schedules II through V controlled substances, PAs must be registered with DEA.
- PA Physician Assistants: Regulations are currently under development that would allow PAs to prescribe and dispense drugs at the direction of licensed physicians. The rules include a formulary that excludes Schedules I and II controlled substances. Until the regulations are promulgated PAs have no prescribing authority.
- Physician Assistants: PAs may write prescriptions and medical orders. PAs employed by physicians, HMOs or other health care delivery organizations may prescribe legend medications and Schedule V controlled substances, medical therapies, device and diagnostics according to guidelines established by their employers. Guidelines are updated annually. PAs prescribing controlled substances must register with the state drug control division and with DEA.

Nurses: NPs have prescriptive authority for legend drugs but not for controlled substances.

SC - Physician Assistants: Regulations are currently under development that would grant PAs dependent authority to prescribe Schedule V controlled substances. The regulations would also establish a formulary and appropriate protocols. Until these regulations are developed and implemented PAs have no prescribing authority.

Nurses: Nurses are certified through the Board of Nursing for dependent prescribing authority.

SD - Physician Assistants: PAs can communicate information regarding Schedules III-V drugs to the pharmacy either in writing or by phone. PAs must act as agents of physicians to Issue prescriptions for controlled substances; the physician decides on drug, dosage, amount and length of therapy.

Nurses: Certified NPs may prescribe under a practice agreement with the supervising physician. NPs act as the agent of the primary supervising physician in providing and prescribing, except for Schedule II controlled substances.

- TN Nurses: Certified NPs may apply to the Board of Nursing for a "certificate of fitness" with privileges to write and sign prescriptions and/or issue non-controlled legend drugs.
- TX Physician Assistants: Physicians may authorize PAs to administer, provide or carry out a prescription drug order (i.e., complete a prescription pre-signed by the supervising physician) in medically underserved areas.

Nurses: ARNPs have prescriptive authority under standing orders or protocols; prescriptions must be "presigned." To be authorized to prescribe the ARNP must serve certain medically underserved populations.

UT - Physician Assistants: PAs may, in accordance with an approved utilization plan, prescribe Schedule IV and V controlled substances for a period not to exceed seven days.

Nurses: All NPs who practice with a physician can apply for prescriptive privileges in accordance with protocols between the NP and physician. NPs can prescribe controlled substances III-V.

- VT Physician Assistants: PAs may prescribe only drugs selected by the supervising physician from the board-approved drug list. The board's approved drug list contains 25 categories. Some categories, such as heavy metal antagonists, antineoplastics, coagulation agents, cardiovascular drugs and oxytoxics, require additional protocols describing in detail the conditions under which the PA will be prescribing. The physician may delegate the prescribing of controlled substances in any of the categories.
- VA Physician Assistants: Regulations are currently being developed that would give PAs dependent authority to prescribe non-controlled substances. The regulations will include a formulary of specific drugs and devices a PA may prescribe under a written protocol with the supervising physician.

Nurses: ARNPs may prescribe most Schedule VI drugs under the supervision of a licensed physician.

- WA Physician Assistants: PAs may issue written or oral prescriptions when approved by the board and assigned by the supervising physician. Prescriptions for drugs in Schedule II-V may be issued for patients under the care of the sponsoring physician.
- WV Physician Assistants: PAs in all settings may issue prescriptions at the direction of their supervising physician. A state formulary excludes Schedule I and II controlled substances, anticoagulants, antineoplastics, radiopharmaceuticals, general anesthetics, and radiographic contrast materials. Drugs listed under Schedule III are limited to a 72-

hour supply without refill. Medical board rules exclude parenterals, except insulin and epinephrine, from the formulary.

Nurses: ARNPs have limited authority to prescribe, including some controlled substances.

- WI Physician Assistants: Supervising physicians may direct a PA to prepare a prescription order for non-controlled substances if the PA prepares the prescription order only in patient situations specified and described in written protocols; the PA consults directly with the physician, when practicable, prior to preparing a prescription; and the prescription contains the name and address of the physician and PA.
- WY Physician Assistants: PAs may prescribe medications as an agent of the supervising physician, except for Schedule I and II controlled substances. When prescribing controlled substances the supervising physician's DEA number is used.

Nurses: Current legislation states that nurses have prescribing and dispensing capabilities under a "collaborative agreement" with a physician. The Attorney General is currently in the process of determining whether this "collaborative agreement" constitutes independent or dependent prescribing authority. Until the Issue is resolved nurses do not have prescriptive authority for controlled substances.

d Cardinal Health

Tom Blaylock/National Specialty Serv.

John Dewees/Marmac

Paul Exicy/Ohio Valley

Rick Gliot/Chapman

Pat Jensen/Syrocuse

Ben Jones/Balley

Brian Landry/Mississippi

Doug Pace/Florida

John Roth/Solomons

Roy Stromski/Daly

Carol Verrastro/Ellicott

CC:

George Bennett/Dublin

Pete Westermann/Dublin

Linda Zarlengo/Dublin

At a recent meeting with DEA in Washington, D.C., Jim Pacella, DEA's Policy Unit Chief, discussed DEA registration verification issues with NWDA's Regulatory Affairs Committee. The points Mr. Pacella made are summarized as follows:

September 7, 1993

DEA Registrations

Steve Reardon Stime

FROM

SUBJ

- Local DEA offices have been instructed not to verify DEA registrations verbally via the telephone. The reason is that certain wholesalers were using this as the sole means of verifying their customers' DEA registration numbers. Despite these instructions, however, I am aware of local offices that continue to verify numbers over the telephone. My recommendation is that if, in emergency situations, your local DEA office will provide this service, then you should continue to use it as long as the verification is documented on a Regulatory Agency Contact Form. This method, however, should not replace your existing Registration Verification Procedure.
- Local DEA offices should not be verbally issuing DEA registration numbers upon
 inspections of new registrants. DEA's policy is that a person is not registered until the
 registration certificate is issued. Although DEA Washington denies it, I know that
 local DEA offices continue this practice. Again, if your local DEA offices operate in
 this manner, you should take advantage and service your customer as long as you
 document the verification and request from your customer a copy of the certificate
 immediately upon receipt.

- A 60-90 day registration renewal grace period exists during which time you can
 continue to sell to customers who have yet to receive their renewed registration. I
 would recommend that you obtain a copy of the customer's renewal application and
 processed check if possible.
- For those accounts who operate on a physician's DEA registration, the physician's name should also appear on the records for that account; i.e., the invoice should show:

ABC Clinic Dr. John Smith

If you have any questions regarding these issues, please call.

2



U.S. Department of Justice

2

Drug Enforcement Administration

Washington, D.C. 20537

NOV 2 9 1993

Ms. Diane P. Goyetta
Director of Regulatory Affairs
National Wholesale Druggists' Association
1821 Michael Faraday Drive
Suite 400
Reston, Virginia 22090-5348

Dear Ms. Goyette:

This is in response to your correspondence of November 4, 1993, requesting information on any written clarification of security issues prepared by the Drug Enforcement Administration concerning specifications for cages and security containers. The Office of Diversion Control (OD) routinely disseminates security information to its field offices as part of its effort to insure uniform interpretation and application.

Recently, two security notices were prepared and distributed to the field Diversion Investigators. One addressed the new GSA specification revision for Class 5 security containers and the other addressed the cage configuration utilized for the storage of Schedule III-V controlled substances. The following is a synopsis of those two notices:

Class V Security Containers: This notice covered the General Services Administration's (GSA) specification revisions for improved, manipulation-resistant combination locking devices used on GSA Class 5 and 6 security containers and vault doors. This revision was intended to counter surreptitious entry using an auto-dialing device and/or radiological or emanations analysis. As a result, the specifications where changed to read as follows:

"20 man-hours against surreptitious entry; 30 man-minutes against covert entry; and 20 man-hours against radiological techniques."

This notice further stated that only one lock, the Mas-Hamilton X-07, meets the new specifications without modifications. It further explained that the security

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standards listed in 21 CFR 1301.72(a)(1)(i) and 1301.72(a)(3)(ii) have not been revised to agree with the new GSA specifications.

Lastly, the notice re-emphasized the fact that the regulations do not require a registrant to utilize a GSA Class 5 container. Instead, the regulations spell out the minimum security requirements for a security container or vault door used for the storage of Schedule I and II controlled substances. There are several security containers which, when equipped with a Group 1-R three position dial-type combination lock, meet the current Federal requirements.

Schedule III-V Cage Specifications: This notice clarified the construction specifications for cages utilized for the storage of Schedule III-V controlled substances. As described in 21 CFR Section 1301.72(b) (4) (ii), a cage's mesh construction cannot have openings greater than 2 1/2" across the square. The confusion existed with the phrase "across the square" which is not a standard size measurement used by cage manufacturers to describe mesh fabric. The industry measurement for mesh size is the minimum distance between the wires forming the parallel sides of the mesh.

Some field offices were interpreting this measurement to be the diagonal distance from corner to corner, while other offices were using the distance between the parallel sides of the mesh configuration. A size comparison of the two options shows a substantial mesh size difference.

Based on this comparison and the intent of this regulation, it was decided that the 2 1/2" measurement has to be interpreted as the greatest point of separation in the mesh configuration. Another way of describing this regulation requirement is that the mesh size cannot exceed 1 3/4" by industry standards.

I trust that the above information adequately addresses your request. If you have any additional questions, please do not hesitate to contact this office.

Sincerely,

William C. Reinig Security Specialist

Office of Diversion Control



TO

Tom Blaylock

Brendan Connolly

Paul Exley

Ben Jones

David Kozaczka Brian Landry

George Oughterson

Doug Pace John Roth

Roy Stromski

Mike Vaughan Carol Verrastro

CC:

George Bennett
Pete Westermann

DATE

February 14, 1994

FROM

Steve Reardon

DEA Security Issues

Attached, for your information and your DEA file, is a letter from Bill Reinig, DEA Diversion Security Specialist, to Diane Goyette, NWDA Director of Regulatory Affairs. The purpose of the letter is to summarize two security notices recently distributed to DEA field offices. One addressed a new GSA Class V specification for vault door construction; the other, controlled substance cage construction.

Evidently, as a result of the change in the GSA Class V vault door specifications, some local DEA offices were requiring vault doors of this new design. Reinig, in the letter, explains that while the GSA description did change, DEA regulations do not automatically require use of a GSA Class V door. Several different designs can meet DEA requirements. The cage construction section is self-explanatory.

If you have any questions, please call.

Attachment



Càrdinal Health, Inc. INTEROFFICE MEMORANDUM

CC:

Joe Neary/Whitmire

Pete Westermann/Dublin

To: Martin Alires/Syracuse

Bill Becker/Florida

Brendan Connolly/Ellicatt

Mike Davison/Behrens-Lubbock

John Dewees/Marmac

Paul Exicy/Ohio Valley

Jack George/Behrens-Waco

Ben Jones/Chapman

Les Killebrew/Mississippi

Harry Myers/Humiston Keeling

George Oughterson/PRN

John Roth/Solomons

Roy Stromski/Daly

Loren Todd/Bailey

From: Steve Reardon

interpretation is as follows:

Date: July 28, 1994

Re: Order Forms (DEA Form 222)

Attached for your information and your DEA file is a letter issued by DEA to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed. The regulatory

 When a purchaser has used five lines on a DEA Form 222 to order controlled substances, and two lines contain entries for the same product and package size, the number of items ordered would be four. If the purchaser erroneously indicated that five items had been ordered, DEA would deem this a minor error which could be corrected.

Please read the letter for the specifics of this interpretation and pass the information on to the appropriate versonnel in your division.

If you have any questions, please call.

Attachment

FOIA Confidential Treatment Requested By Cardinal



Cardinal Health, Inc. INTEROFFICE MEMORANDUM

To:

Distribution

From:

Steve Reardon, Joe Neary

Date:

August 12, 1994

Re:

Reverse Management Systems (3CI) Waste Disposal Program

Cardinal Health, Inc., has entered into an agreement with Reverse Management Systems (3CI) to dispose of our non-hazardous waste, including controlled substances, legend drugs, OTC items, and aerosols. Reverse Management Systems is registered with the Drug Enforcement Administration in Schedules II, III, IV and V, the Texas Department of Health, and the Texas Department of Public Safety. This registrant status allows them to receive and take possession of controlled substances and legend drugs for the purpose of disposal via incineration.

The pricing schedule is as follows:

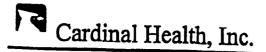
1-24,999	pounds	\$.045/lb.
25T-74,999	pounds	\$.043/lb.
75T-99,999	pounds	\$.041/Jb.
> 100 T	pounds	\$.039/Ib.

The total pounds will be counted over a twelve-month period that will start with our first shipment. The steps to facilitate this process are outlined on the following page.

It is strongly recommended that this service be our sole method of disposal so that we may take advantage of volume discounts and assure compliance with applicable Federal, State, and local regulations. We believe that Reverse Management Systems (3CI) can provide us with a simple, efficient, and economical means to manage pharmaceutical waste. Please contact Joe Neary or me if, for some reason, you do not intend to utilize this service.

If you have any questions, please call.

Attachment



PREPARING PRODUCT FOR DESTRUCTION

STEP ONE:

To arrange for destruction, contact:

Mr. Dennis Ingles, Operations Manager Reverse Management Systems DEA Number RE0196611 201 San Augustine Street Center, Texas 75935

1-800 RX REVERSE (797-3837), or Fax 1-409-598-9539

STEP TWO:

Reverse Management Systems will provide you with DEA 222 Forms for your Schedule II products.

STEP THREE:

Create a debit memo or zero dollar invoice to Reverse Management Systems. This will serve as documentation of the transfer and create required records (ARCOS, etc.).

STEP FOUR:

When preparing product for shipment:

- 1. Verify that each return is packed according to the products on the schedule II form.
- 2. Segregate, and package separately, all other schedules from the legend products.
- 3. Pack aerosols separately.
- 4. Note that legend and OTC product do not need to be packaged in any special order.
- 5. Notify Reverse Management Systems by telephone or fax as to when shipment will be
- 6. Attach an A.O.D. tag to the top of the box for all orders to be shipped UPS. All other shipments must have some other proof of delivery receipt.
- 7. Include a copy of the debit memo or invoice with the shipment.

STEP FIVE:

Upon completion of the products' incineration, you will receive the following receipts:

- A copy of the completed DEA Form 41. a)
- A detailed burn report, itemizing each box with third party verification. b)
- An invoice detailing the amount based on per pound price. C)
- Documentation showing the accurate weight and the actual destruction, by incineration date, verified by third party municipality.

FOIA Confidential Treatment Requested By Cardinal



TO:

Division Managers / Directors of Operation

FROM:

Steve Reardon / twe

DATE:

June 28, 1995

SUBJECT:

Regulatory Reminder

CC:

Michael Proulx Joe Neary

Art Hammerschmidt

Carol Verrastro

When providing back-up delivery service to another division's customers there are licensing and record keeping issues that must be addressed in order to assure compliance with applicable regulatory requirements. These requirements are as follows:

LICENSING:

Transactions between divisions (except in Georgia and Ohio) qualify for an intra-company exemption, and state licensure is not required. Shipping prescription drugs and/or controlled substances direct to customers within a state requires licensure in most instances. The attached sheet identifies where Cardinal divisions are currently licensed and lists those states where out-of-state licensure is not required. This should assist you in identifying where to go for back-up.

RECORD KEEPING:

If you ship prescription drugs and/or controlled substances directly to another division's customer, your records (invoices, computer-generated sales history reports, ARCOS reports, etc.) must show that customer as the recipient of the product. The Prescription Drug Marketing Act (PDMA) and DEA regulations require wholesalers to maintain records of all transactions regarding the receipt and distribution of prescription and controlled drugs. These records must identify the "ship to" location.

We understand the importance of being able to provide this service to our customers. Our intention is not to restrict your ability to do so. Our purpose is to inform you of the regulatory requirements that must be met when doing so.

Joe Neary and I will work with our MIS groups to explore system support for the record keeping issues. In the interim, we are open to suggestions.

I hope this memorandum clearly identifies the issues at hand. If you have any questions or comments, please contact the Corporate Compliance Department at (614) 799-6050.

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U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

SEP 1 4 1995

Ms. Diane Goyette
National Wholesale Druggists'
Association (NWDA)
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

The Drug Enforcement Administration (DEA) is pleased to announce that the DEA Form 222 (U.S. Official Order Form - Schedule I and II) used to purchase controlled substances from DEA registrants has been changed for clarification purposes. The former line entitled "Number of Lines Completed" has been changed to "Last Line Completed".

This change was made as a result of requests made by DEA registrants to avoid confusion associated with the former requirement for an entry to be made for "number of lines completed". The new forms are already being distributed. Supplies of the old forms should continue to be used until they are depleted.

Please advise your membership of this change. We have enclosed a sample article which may be used for your publications. It is hoped that this change will obviate many problems associated with the former design of the form. If you have any further questions, please contact the Liaison and Policy Section at (202) 307-7297.

6. Thomas Gitchel, Chief

Liaison and Policy Section
Office of Diversion Control

Enclosure

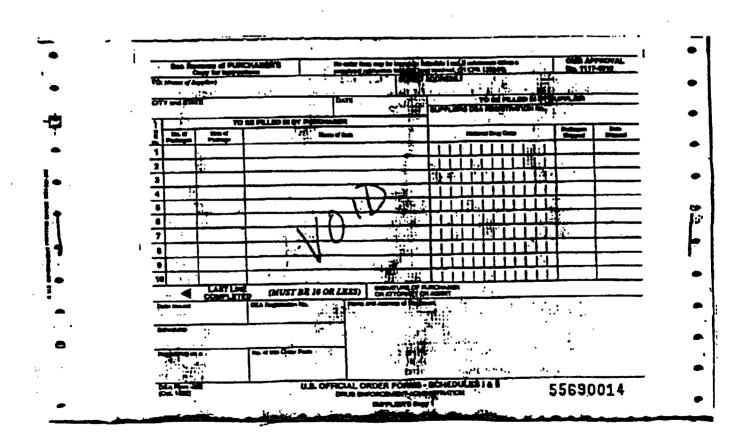
DEA CHANGES ORDER FORM (DEA-222)

The Drug Enforcement Administration (DEA) has announced that, at the request of registrants, a change has been made to the U.S. Official Order Form for Schedule I and II controlled substances (DEA-222). This change has been made for clarification purposes and involves the replacement of the line entitled "Number of Lines Completed" with "Last Line Completed".

The instructions pertaining to the change which appear on the reverse of each individual form indicate under item "8" the following: "Enter the last line completed - this generally should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it."

While DEA hopes that this clarification will eliminate much of the confusion the language of this part of the order form has caused some registrants over the years, they realize that errors will still occur due to misinterpretation. When it is clear to the supplier that the number of the last line completed has been incorrectly noted due to misinterpretation, rather than an attempt to facilitate diversion, the DEA form 222 should not be rejected.

The new clarified forms have already begun to be distributed although old forms should continue to be used until depleted.



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U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

JUL 1 8 1996

Ms. Diane Goyette
Director of Regulatory Affairs
National Wholesale Druggists Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

Thank you for your letter of April 29, 1996, voicing your organization's satisfaction with the April 17, 1996 semi-annual meeting with your membership. I know I speak for all Drug Enforcement Administration (DEA) personnel present at that meeting, in conveying their appreciation for the information presented and the cooperation received.

There are several issues that have been long-standing and we would like to bring you up to date with current activities. The proposed rule on freight forwarding has cleared DEA and is ready to be forwarded to the Department of Justice (DOJ) and the Office of Management and Budget (OMB) for their approval. The DEA ARCOS Unit has resolved the problem of "inadvertent under-reporting" that was attributed to differences in National Drug Code Numbers (NDC) pertaining to sizes. The ARCOS Unit has been able to take care of this problem internally without any further involvement of ARCOS participants.

The last issue centers around delivery of Schedule II order forms by drivers and the associated distribution scenarios. DEA has carefully reviewed the scenarios discussed at the April 17, 1996, meeting and has approved the following circumstances in which driver handling of Schedule II Order Forms (DEA Form 222) will be permitted, and the circumstances under which we will allow DEA Forms 222 to be transmitted by facsimile. DEA will permit the driver to handle DEA Forms 222 provided they are carried in a sealed envelope. DEA will permit the "faxing" of DEA Forms 222 by the customer to the DEA registered distribution center, in order to facilitate the expedient filling of the DEA Form 222. The distributor may prepare the order

FOIA Confidential Treatment Requested By Cardinal

from the facsimile and then compare the prepared order with the controlled substances, when the original DEA Form 222s arrive with the driver. Under no circumstances will DEA permit the driver to have the sole responsibility for reconciliation of the pre-prepared order with the actual DEA Form 222. DEA also does not approve of the scenario that allows the driver to "fax" the copy of the order form at the cross-docking facility. The cross-docking facility should only be used for the temporary storage of controlled substances in transit and DEA will not recognize any other activity, such as "faxing", at the facility. Further, the driver should have no knowledge as to the contents of the DEA Form 222. Also, it is the opinion of DEA that allowing the drivers to be responsible for sole reconciliation of Schedule II orders does not provide the "special handling" of Schedule II orders that the Controlled Substances Act mandates and the diversion possibilities presented by this scenario are obviously more plentiful.

Please convey this decision to your membership. We will inform all of our field offices of this approved procedure, in the hope that it will prevent admonishments such as the one that one of your members was given for allowing the driver to transport the DEA Forms 222. As always, it was a pleasure meeting with you and your membership. If you have any questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincereav

G. Thomas Gitchel, Chief Liaison and Policy Section Office of Diversion Control



U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

AUG 2 8 1996

Ms. Diane Goyette Director of Regulatory Affairs P.O. Box 2219 Reston, Virginia 22090-0219

Dear Ms. Goyette:

Reference is made to our recent meeting regarding the facsimile transmission of DEA forms 222 from retail pharmacies to distributors. As I advised you at that time, the Drug Enforcement Administration (DEA) will permit the facsimile transmission of an executed DEA form 222 directly from a retail pharmacy to a distributor to facilitate filling of an order, provided that the facsimile copy is compared with the original copy prior to shipping the order. It is acceptable, although in our view, not desirable, to permit a proprietary driver, acting as an agent/employee of the distributor, to "fax" a DEA form 222 on behalf of the pharmacy, to the distribution center. The practice of allowing common or contract carriers to "fax" DEA forms 222 to distribution centers, however, is not in the public interest and does not effectively guard against diversion.

We realize that distribution centers adopted procedures for facsimile transmission of DEA forms 222 to expedite delivery of controlled substances to their customers. Nevertheless, we are very concerned that a practice that enables common or contract truck drivers, who are subject to only limited security checks and controls, to know exactly what a particular shipment of drugs will contain, poses a significant threat of diversion.

We urge your members, therefore, to cease this practice as soon as possible. It has been represented that the practice of "faxing" DEA forms 222 by common and contract carriers is widespread and well-established in many of your members' distribution centers. Therefore DEA will recognize a transition period until December 31, 1996 to discontinue this practice.

If you have any questions, please let me know.

Sincerely

G. Thomas Gitchel, Chief Liaison and Policy Section Office of Diversion Control

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U. S. Department of Justice

Drug Enforcement Administration Office of Diversion

Washington, D.C. 20537

#27 1 7 1997

Diane P. Goyette, Director Regulatory Affairs National Wholesale Druggists' Association P.O. Box 2219 Reston, Virginia 20195-0219

Dear Ms. Goyette:

This is in response to your letter of August 13, 1997, regarding the proper procedure for documenting liquid controlled substance loss through accidental breakage of its container.

1. You ask whether such loss should be reported using a DEA Form-41, "Registrants Inventory of Drugs Surrendered," or a DEA Form-106, "Report of Theft or Loss of Controlled Substances."

When a bottle containing a controlled substance is accidentally broken, the registrant should report the loss on a DEA Form-41. The DEA Form-41 is used to report the disposal of controlled substances in the registrant's possession. As you are aware, DEA requires that the loss be recorted in order to account for all dispositions of the controlled substance within the closed distribution system. Any remaining controlled substance, with the container labeling, should be disposed of in accordance with Title 21, Code of Federal Regulations (21 CFR), Section 1307.21. A registrant should use a DEA Form-106 to report an unaccounted for loss, a theft or a loss in transit.

 You also ask what a distributor should use in the "Associated Registrant Number" and "DEA Order Form Number" fields of the ARCOS report.

The DEA ARCOS Reporting Manual states that the registrant, in accounting for the loss on an ARCOS report, should place a tode "Y" in the transaction field, and the DEA Area Office Registration Number in the "Associated Registrant Number" field. The "DEA Order Form Number" field should remain blank.

3. And lastly, you inquire whether DEA requires a distributir to keep the pieces of broken obtale as evidence of the incident.

DEA does not require a registrent to keep the broken bottle pieces as evidence of the incident, but does require that the loss be accumented as outlined abovo.

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I trust that the foregoing adequately answers your questions. If we may be of further assistance, please to not hesitate to contact this office at (202, 307-7297.

SincereZy,

fice of Diversion Control

Divisional Liccusure By State

Alabama	Alaska	Arizona	Arkansas	California	Colorado
Calumet City	Auburn	Phoenix	Cord Logistics	Auburn	Albuqueraue
Cord Logistics			Jackson	Calumet City	Cord Logistics
Jackson			Kansas City	Cord Logistics	Denver
Knoxville			Lakeland	National PharmPak	Lakeland
Lakeland			NSS-Albuquerque	NSS-Nashville	NSS-Nashville
NSS-Albuquerque			NSS-Nashville	Ontario	PharmPak
NSS-Nashville			St. Louis	Sacramento	Williams Drug
PharmPak			Williams Drug	Union City	
Savannah	Out of State Licensure	Out of State Licensure		Valencia	
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Connecticut	Delaware	Dist. of Col.	€ Florida	Georgia	Georgia cont'd.
Allentown	Allentown	Allentown	Calumet City	Aubum	Salt Lake City
Boston	Boston	Cord Logistics	Cord Logistics	Boston	Savannah
Cord Logistics	Cord Logistics	NSS-Albuquerque	Jackson	Calumet City	Waco
Hartford	Lakeland	NSS-Nashville	Knoxville	Cord Logistics	Wheeling
Lakeland	NSS-Albuquerque	Wheeling	Lakeland	Denver	Winston-Salem
NSS-Albuquerque	NSS-Nashville		NSS-Nashville	Knoxville	Williams Drug
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	Lakeland	Cord Logistics	Cord Logistics	Cord Logistics	Lakeland
	Salt Lake City	Kansas City	NSS-Nashville	Kansas City	NSS-Nashville
	Williams Drug	Lakeland	PharmPak	Lakeland	PharmPak
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Divisional Licensure By State

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	Cord Logistics	Allentown	Allentown	Boston	10 mg
	Jackson	Boston	Boston		Chicago
	Knoxville	Cord Logistics	Cord Logistics		Cord Logistics
	Lakeland	Lakeland	Lakeland		akeland
	NSS-Albuquerque	NSS-Albuquerque	NSS-Albuquerque		Milwairkee
	NSS-Nashville	NSS-Nashville	NSS-Nashville	,	NSS-Albuquerone
	PharmPak	PharmPak	PharmPak		NSC-Nachville
	Waco	Syracuse	Wheeling		Dhambak
	Williams Drug	Williams Drug	Williams Drug		Syracise
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Lakeland	Knoxville	Cord Logistics	Sacramento	Denver	
Minneapolis	Lakeland	Denver	Salt Lake City	Lakeland	
NSS-Albuquerque	NSS-Albuquerque	Houston	St. Louis	ASS-Albudian	-
NSS-Nashville	NSS-Nashville	Jackson	Williams Drug	NSS-Nashville	
PharmPak	PharmPak	Kansas City	Winston-Salem	Saft Lake City	
Williams Drug	Williams Drug	Knoxville	PharmPak	Williams Drug	Out of State Licensure
		Lakeland)	Not Required
Nevada	New Hampshire	New Jersey	New Mexico	New York	North Carolina
Cord Logistics	Allentown		Albuquerque	Allentown	Cord Logistics
Lakeland	Boston		Cord Logistics	Boston .	Knoxville
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Divisional Licasure By State

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Boston NSS-Nashville
Calumet City
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South Carolina South Dakota
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Divisional Discoution By State

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Boston	Cord	Boston	Cord	National PharmPak
Cord	National PharmPak	Cord	Lombard	NSS-Nashville
Hartford	NSS-Nashville	Hartford	Milwaukee	Minneapolis
National PharmPak	Wheeling	National PharmPak	National PharmPak	Williams Drug
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Cord	Cord	Cord	Cord	Allentown
Kansas City	Denver	Denver	NSS-Nashville	Boston
Lombard	NSS-Nashville	Kansas City	Phoenix	Cord
National PharmPak	Salt Lake City	National PharmPak	Sacramento	Hartford
NSS-Nashville	Williams Drug	NSS-Nashville	Salt Lake City	NSS-Nashville
St. Louis			Valencia	Williams Drug
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New Mexico	New York	North Carolina	- North Dakota	(= = 0 h o = = 1
Albuquerque	Allentown	Cord	Cord	Aurora
Cord	Boston	Knoxville	Minneapolis	Cord
National PharmPak	Cord	National PharmPak	NSS-Nashville	Knowille
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	Williams Drug	Winston-Salem		Williams Drug
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Divisional Dis ... oution By State

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2 Pennsylvania	Boston	Cord	National PharmPak	NSS-Nashville	Pennsylvania	Syracise	ON BUCCOO	Wheeling	Wheeling Williams Drug	Wheeling Williams Drug	Wheeling Williams Drug	Wheeling Williams Drug Williams Drug Cord National PharmPak	Wheeling Williams Drug Williams Drug Cord National PharmPak NSS-Nashville	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane	Wheeling Williams Drug Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug	Wheeling Williams Drug Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug Cord	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug Cord Cord	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug Cord Denver NSS-Nashville	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug Cord Denver NSS-Nashville	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug Cord Denver NSS-Nashville Salt Lake City	Wheeling Williams Drug Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug Cord Denver NSS-Nashville Salt Lake City
. — Отедол:	Auburn	Cord	National PharmPak	NSS-Nashville	Salt Lake City	Williams Drug				Sexes:	Z. TÖXƏSI Albuquerque	Albuquerque Cord	Albuquerque Cord Houston	Albuquerque Cord Houston National PharmPak	Abuquerque Cord Houston National PharmPak NSS-Nashville	Abuquerque Cord Houston National PharmPak NSS-Nashville	Abuquerque Abuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug Aurora	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug Williams Cord Cord	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug Aurora Cord Milwaukee	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug Warora Cord Milwaukee Minneapolis	Abuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug Aurora Cord Milwaukee Minneapolis National PharmPak	Abuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug Walliams Drug Aurora Cord Minneapolis National PharmPak NSS-Nashville
Oklahoma	Cord	Kansas City	National PharmPak	NSS-Nashville	Waco	Williams Drug				e Tennessee	Cord	Cord	Cord Lackson Sackson	Cord Jackson National PharmPak NSS-Nashville	Cord Jackson National PharmPak NSS-Nashville Williams Drug	Cord Jackson National PharmPak NSS-Nashville Williams Drug	Cord Lackson National PharmPak NSS-Nashville	Cord Lord Jackson National PharmPak NSS-Nashville Williams Drug	Cord Jackson National PharmPak NSS-Nashville Williams Drug	Cord Jackson National PharmPak NSS-Nashville Williams Drug MesteVIrigijnia	Cord Jackson National PharmPak NSS-Nashville Williams Drug Allentown Cord Knoxvile	Cord Jackson National PharmPak NSS-Nashville Williams Drug Allentown Cord Knoxvile National PharmPak	Cord Jackson National PharmPak NSS-Nashville Williams Drug Allentown Cord Knoxville National PharmPak NSS-Nashville	Cord Jackson National PharmPak NSS-Nashville Williams Drug West Wirginia Allentown Cord Knoxvile National PharmPak NSS-Nashville

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